

## **AIM OF THE WORK**

The aim of this work is to evaluate the effect of Amantadine in improving neurorecovery in Traumatic Brain Injury.

## **PATIENTS**

After approval of the local ethical committee & having an informed written consent from every patient or relatives, this study carried out in critical care department unite 1&3 in Alexandria main university Hospital on 60 Patients of both sex , aged from 16 to 75 years old fulfilled clinical criteria for adult patient who directly admitted to the Critical Care Department with a TBI resulting from a motor vehicle crash (MVC) and a GCS score of  $\leq 10$ , where enrolled in the study within 4 days to 4weeks of admission to acute care.

### **The inclusion criteria of the Patients were as follows:**

1. Age 16–75 years of both sex.
2. Enrolled in the study within 4 days to 4weeks of admission to acute care and meet the following criteria:
  - a. GCS score of 10 or less within the first 24 hours of injury.
  - b. Posttraumatic amnesia of at least 1 week.
  - c. Loss of consciousness immediately after a motor vehicle crash.

### **Exclusion criteria**

1. Refusal to participate.
2. Females of child bearing potential or pregnant females
3. Patients receiving any other investigational drug within 30 days of injury.
4. Subjects known to have severe ischemic heart disease or congestive heart failure, myocardial infarction, spinal cord injury with ongoing deficits or cancer that may affect the assessment of therapy.
5. History of major depression requiring ongoing medication with buspirone or tricyclic antidepressants.
6. Subjects who had any type of penetrating head injury.
7. Subjects receiving long term steroid therapy.
8. Prior significant TBI or brain tumor.
9. Patients with renal failure.

## METHODS

The study population consisted of patients who were directly admitted to the critical care Department with a TBI resulting from a motor vehicle crash (MVC) and a GCS score of  $\leq 10$ .

The trial was a randomized by closed envelop method, placebo-controlled crossover study conducted primarily to evaluate safety with a secondary goal to obtain efficacy data on the use of amantadine in acute TBI.

- ❖ Group 1 (n = 30) received amantadine in the first 4 weeks after injury and then placebo for the second 4 weeks.
- ❖ Group 2 (n = 30) received placebo in the first 4 weeks and amantadine in the second 4 weeks.

### Acute Neurological Management

During the initial hospital admission, all patients were treated according to neurotrauma standard protocol, These neurotrauma protocols were outlined in the Guidelines for the Management of Severe Traumatic Brain Injury.<sup>(113)</sup>

### Pharmacological agents

Amantadine, 200 mg/day, or a placebo were delivered in a double-blind randomized crossover study for 4 weeks (delivered in divided doses in the morning and at noon to improve alertness during the day).

Patients were not participants in any other interventional studies aimed at enhancing neurorecovery to restrict medications that may be detrimental to neurological recovery in acute CNS injury. Particular attention was paid to medications that may result in blockade of dopamine receptors.<sup>(114)</sup>

All patients were start medication as soon as they were off pressors, and the neurosurgical consultant/staff managing their acute care deemed them able to tolerate the delivery of amantadine elixir.

No subject started the trial earlier than 4 days or later than 4 weeks after injury.

- Informed consent was taken from relatives of patients according to ethical committee of Alexandria Faculty of medicine.
- The following data were collected:
  1. Demographic data as name, age or sex.
  2. Medical history.
  3. Full clinical examination and ECG.
- Laboratory examinations including: sodium, potassium, bicarbonate, glucose, urea nitrogen, creatinine and complete blood count obtained weekly for 8<sup>th</sup> weeks .

### **Primary outcome**

Patients had been followed up weakly for 8 weeks for assess neurological recovery using four different scales:-

1. The Disability Rating Scale (DRS): assesses function on eight activities, including eye-opening, communication, and motor response, with the highest score of 29 indicating the worst function. <sup>(115)</sup> Appendix: A
2. The Mini-mental Status Test (MMST): is a brief 30 point questionnaire test that is used to screen for cognitive impairment, it take about 10 minutes and examines functions including arithmetic, memory and orientation with score greater than or equal to 25 points (out of 30) indicates a normal cognition. <sup>(116)</sup> Appendix: B
3. The Glasgow Outcome Scale (GOS): is applies to patients with brain damage allowing the objective assessment of their recovery in five categories death, persistent vegetative state, severe disability, moderate disability and low disability, score 5 indicate good recovery with Resumption of normal activities even though there may be minor neurological or psychological deficits. <sup>(117)</sup> Appendix: C
4. The Galveston Orientation and Amnesia Test (GOAT) is a measure of attention and orientation especially to see if patient has recovered from post traumatic amnesia after TBI, Score of 78 or more on three consecutive occasions is considered to indicate that patient is out of post-traumatic amnesia. <sup>(115)</sup> Appendix: D

### **Secondary outcome**

Patients were followed until discharge, not more than 56 days and the secondary outcome were recorded as regards:

- Duration of stay "days" in intensive care unit.
- Complications: long standing complication of trauma patients in the ICU and complication related to amantadine use.

### **Statistical analysis of the data<sup>(\*)</sup>**

Data were fed to the computer and analyzed using IBM SPSS software package version 20.0. (\*\*) Qualitative data were described using number and percent. Quantitative data were described using range (minimum and maximum), mean, standard deviation and median. Comparison between different groups regarding categorical variables was tested using Chi-square test. When more than 20% of the cells have expected count less than 5, correction for chi-square was conducted using Fisher's Exact test or Monte Carlo correction.

The distributions of quantitative variables were tested for normality using Kolmogorov-Smirnov test, Shapiro-Wilk test and D'Agstino test, also Histogram and QQ plot were used for vision test. If it reveals normal data distribution, parametric tests was applied. If the data were abnormally distributed, non-parametric tests were used.

For normally distributed data, comparison between two independent population were done using independent t-test, also paired t-test is used to analyse two paired data. For

abnormally distributed data, comparison between two independent populations were done using Mann Whitney test.

To compare between the different periods Wilcoxon signed ranks test was applied. Significance of the obtained results was judged at the 5% level.

\*Kotz S, Balakrishnan N, Read CB, Vidakovic B. Encyclopedia of statistical sciences. 2nd ed. Hoboken, N.J.: Wiley-Interscience; 2006. Kirkpatrick LA, Feeney BC. A simple guide to IBM SPSS statistics for version.

\*\*Student ed. Belmont, Calif.: Wadsworth, Cengage Learning; 2013.

## RESULTS

### Characteristics of the study sample:

The study population consisted of patients who were directly admitted to the critical care Department with a TBI from a motor vehicle crash (MVC) and a GCS  $\leq 10$ .

The trial is a randomized by closed envelop method, placebo-controlled crossover study conducted primarily to evaluate safety with a secondary goal to obtain efficacy data on the use of amantadine in acute TBI.

- **Group I:** (n = 30) received amantadine sulfate in a dose of 200 mg iv twice daily in the first 4 weeks after injury and then placebo for the second 4 weeks. A persistent unconsciousness was the main reason for amantadine sulfate treatment.
- **Group II:** (n = 30) received placebo in the first 4 weeks and amantadine sulfate in a dose of 200 mg i.v twice daily in the second 4 weeks.

### I) Demographic data:

#### 1) Sex: (table 2, figure 6)

This study included 49 males (81.6%) and 11 females (18.3%)

Sex distribution in different groups was as follows:

- **Group I:** included 23 males (76.7%) and 7 females (23.3%).
- **Group II:** included 26 males (86.7%) and 4 females (13.3%).

There was no statistically significant difference between the 2 groups as regard sex using Chi-square test ( $\chi^2=1.002$ ) (p=0.317).

#### 2) Age: (years) (table 3, figure 7)

This study included patients with age ranged from 16 to 75 years old.

Age distribution in different groups was as follows:

- **Group I** included patients with age ranged from 16 to 75 years old with Mean  $\pm$  SD (42.10  $\pm$  18.72) and median (38 years).
- **Group II** included patients with age ranged from 16 to 65 years old with Mean  $\pm$  SD (43.40  $\pm$  15.24) and median (44 years).

There was no statistically significant difference between the 2 groups as regard age using Student t-test (t=0.295) (p=0.769).

### II) Comparison between the two studied groups according to medical history of associated diseases (table 4, figure 8)

This study included patients with medical history of several diseases there was no significant difference between the 2 groups as regard past history for patients suffering from congestive heart failure, ischemic heart disease, cancer, renal impairment, hepatic impairment, stroke or Epilepsy.

Table (2): Comparison between the two studied groups according to sex

Cases	Sex	
	Group I (n=30)	Group II (n=30)
1	Female	Male
2	Male	Male
3	Male	Female
4	Male	Female
5	Male	Male
6	Male	Male
7	Male	Male
8	Female	Male
9	Male	Male
10	Male	Female
11	Female	Male
12	Male	Male
13	Male	Male
14	Male	Male
15	Male	Male
16	Female	Male
17	Male	Male
18	Male	Male
19	Male	Male
20	Female	Male
21	Male	Female
22	Female	Male
23	Male	Male
24	Male	Male
25	Male	Male
26	Male	Male
27	Male	Male
28	Female	Male
29	Male	Male
30	Male	Male
Male	23 (76.7 %)	26 (86.7 %)
Female	7(23.3 %)	4 (13.3 %)
Test of sig.	$\chi^2=1.002$	
p	0.317	

p:p value for comparing between the studied groups

 $\chi^2$ : Chi square test

t: Student t-test

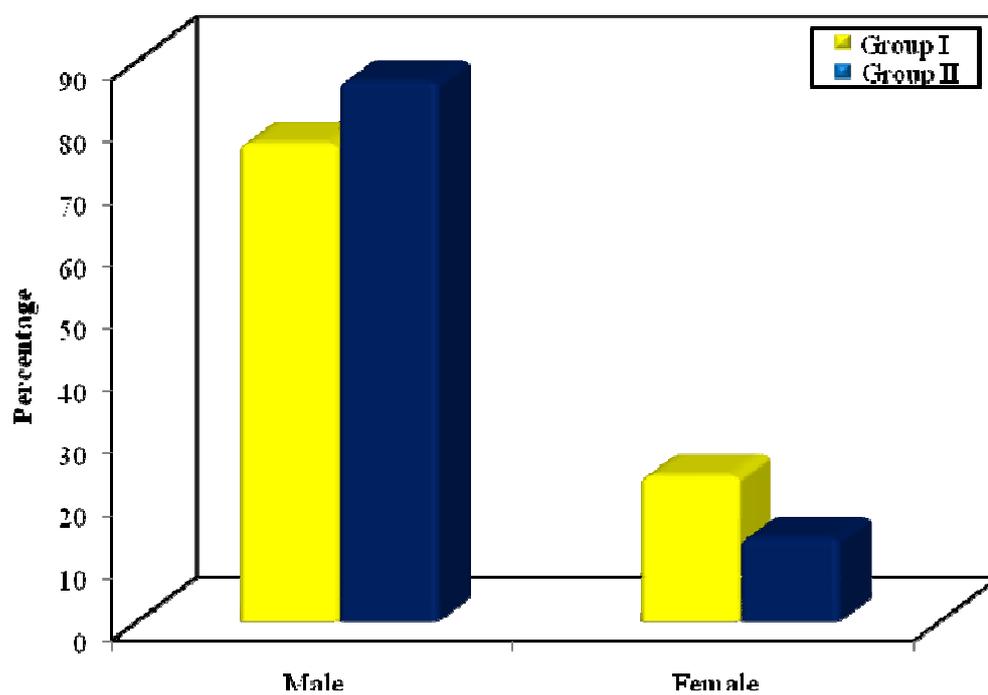
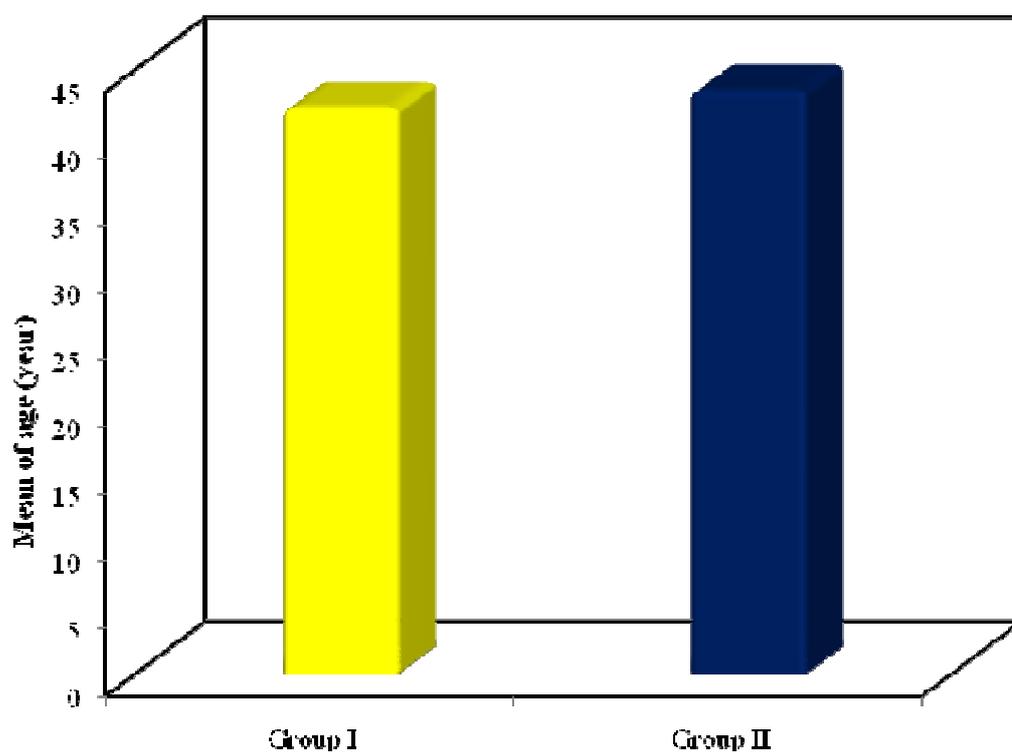


Figure (6): Comparison between the two studied groups according to sex.

Table (3): Comparison between the two studied groups according to age (years)

Cases	Age	
	Group I (n=30)	Group II (n=30)
1	16	39
2	61	58
3	33	47
4	48	16
5	20	65
6	66	44
7	61	64
8	19	32
9	38	57
10	72	23
11	38	63
12	55	46
13	29	21
14	48	33
15	29	24
16	16	44
17	30	65
18	37	64
19	68	44
20	75	37
21	59	28
22	48	58
23	58	32
24	56	45
25	30	57
26	63	29
27	17	63
28	27	43
29	26	38
30	22	23
Min	16.0	16.0
Max	75.0	65.0
Mean	42.10	43.40
SD	18.72	15.24
Median	38.0	44.0
<b>Test of sig.</b>	<b>t=0.295</b>	
<b>p</b>	<b>0.769</b>	

p:p value for comparing between the studied groups  
 $\chi^2$ : Chi square testt: Student t-test

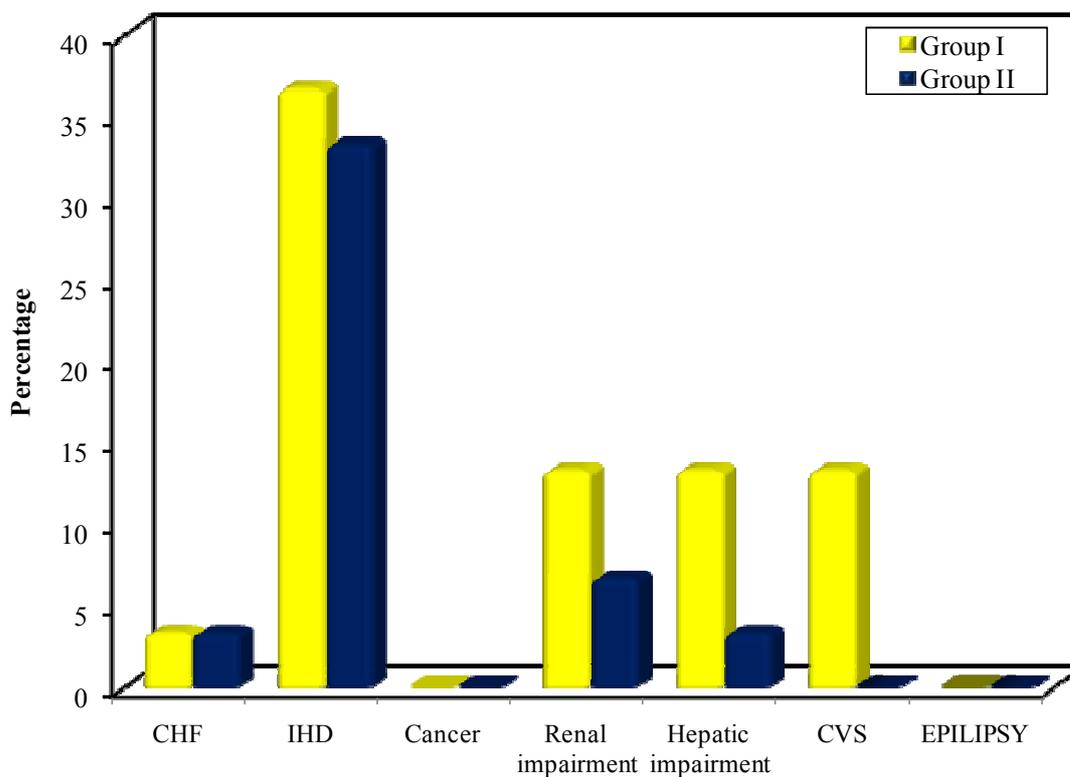


**Figure (7):** Comparison between the two studied groups according to age (years).

**Table (4): Comparison between the two studied groups according to medical history of associated diseases.**

	Group I (n=30)		Group II (n=30)		$\chi^2$	p
	No.	%	No.	%		
<b>Medical history</b>						
CHF	1	3.3	1	3.3	0.0	<sup>FE</sup> p=1.000
IHD	11	36.7	10	33.3	0.073	0.787
Cancer	0	0.0	0	0.0	-	-
Renal impairment	4	13.3	2	6.7	0.741	<sup>FE</sup> p=0.671
Hepatic impairment	4	13.3	1	3.3	1.964	<sup>FE</sup> p=0.353
Stroke	4	13.3	0	0.0	4.286	<sup>FE</sup> p=0.112
Epilepsy	0	0.0	0	0.0	-	-

$\chi^2$ : value for Chi square  
FE: Fisher Exact test



**Fig. (8): Comparison between the two studied groups according to medical history of associated diseases.**

### **III) Laboratory investigation**

#### **1. Comparison between the two studied groups according to sodium levels (Na) mEq/L**

There was no statically significant difference between the patients in group I after one and two months of admission at all time of measurements ( $p=0.118$ ) (table 5) also there was no statistically significant difference in the group II after one and two months of admission at all time of measurements ( $p=0.492$ ) (table 6), but There was statically significant difference between group I and group II after one month of admission ( $p=0.009$ ) and no statically significant difference in the 2nd month ( $p=0.178$ ) (table 7, figure 9).

#### **2. Comparison between the two studied groups according to potassium levels (K) mEq/L**

There was no statically significant difference between the patients in group I after one and two months of admission at all time of measurements ( $p=0.076$ ) (table 8) also there was no statistically significant difference in the group II after one and two months of admission at all time of measurements ( $p=0.274$ ) (table 9).

In compression between group I and group II after one month of admission ( $p=0.800$ ) and second month ( $p=0.214$ ) there is no statistically significant difference (table 10, figure 10).

**Table (5): Comparison between the First four weeks and Second four weeks according to sodium levels (Na) mEq/L in Group I.**

Cases	First four weeks				Second four weeks			
	Na 1	Na 2	Na 3	Na 4	Na 5	Na 6	Na 7	Na 8
1	136.0	134.0	138.0	138.0	140.0	137.0	133.0	135.0
2	137.0	134.0	135.0	136.0	137.0	136.0	138.0	137.0
3	128.0	130.0	133.0	135.0	136.0	136.0	136.5	135.0
4	137.0	138.0	137.0	140.0	135.0	133.6	137.2	135.7
5	133.0	135.0	134.0	137.0	137.0	140.0	138.0	139.0
6	136.0	128.0	130.0	133.0	136.0	135.0	133.0	135.0
7	133.0	140.0	160.0	150.0	145.0	142.0	140.0	141.0
8	136.0	137.0	136.0	135.0	136.0	137.0	136.0	136.0
9	137.0	135.0	140.0	145.0	139.0	135.0	137.0	136.0
10	133.0	132.0	137.0	134.0	140.0	137.0	136.0	135.0
11	139.0	138.0	138.0	137.0	139.0	134.0	137.0	135.0
12	137.0	135.0	136.0	135.0	140.0	138.0	139.0	136.0
13	136.0	135.0	133.0	136.0	138.0	135.0	136.0	137.0
14	134.0	136.0	133.0	138.0	132.0	136.0	135.0	136.0
15	138.0	135.0	136.0	135.0	139.0	136.0	138.0	139.0
16	135.0	137.0	135.0	134.0	138.0	135.0	137.0	135.0
17	139.0	137.0	136.0	138.0	136.0	137.0	136.0	135.0
18	138.0	136.0	137.0	140.0	139.0	138.0	137.0	136.0
19	138.0	136.0	136.0	140.0	138.0	139.0	134.0	135.0
20	133.0	134.0	136.0	137.0	136.0	134.0	136.0	136.0
21	137.0	136.0	139.0	134.0	139.0	138.0	137.0	135.0
22	135.0	136.0	135.0	138.0	139.0	144.0	139.0	140.0
23	132.0	136.0	137.0	135.0	136.0	137.0	140.0	139.0
24	143.0	140.0	144.0	143.0	139.0	136.0	137.0	139.0
25	143.0	145.0	137.0	136.0	153.0	140.0	134.0	139.0
26	132.0	136.0	138.0	136.0	140.0	146.0	150.0	143.0
27	136.0	137.0	138.0	135.0	138.0	136.0	137.0	139.0
28	133.0	136.0	137.0	140.0	145.0	143.0	142.0	139.0
29	137.0	136.0	137.0	139.0	135.0	136.0	135.0	138.0
30	139.0	137.0	136.0	137.0	136.0	135.0	137.0	138.0
<b>Mean</b>	<b>136.0</b>	<b>135.90</b>	<b>137.13</b>	<b>137.53</b>	<b>138.53</b>	<b>137.39</b>	<b>137.26</b>	<b>137.12</b>
<b>± SD</b>	<b>3.16</b>	<b>2.99</b>	<b>4.98</b>	<b>3.60</b>	<b>3.81</b>	<b>3.04</b>	<b>3.13</b>	<b>2.15</b>
	<b>1<sup>st</sup> month</b>				<b>2<sup>nd</sup> month</b>			
<b>Min</b>	131.50				134.75			
<b>Max</b>	145.75				144.75			
<b>Mean</b>	136.64				137.57			
<b>SD</b>	2.77				2.37			
<b>Median</b>	136.25				136.88			
<b>Z<sub>1</sub></b>	1.564							
<b>p<sub>1</sub></b>	0.118							

Z<sub>1</sub>: Z for Wilcoxon signed ranks test

p<sub>1</sub>: p value for Wilcoxon signed ranks test for comparing between 1<sup>st</sup> and 2<sup>nd</sup> month

**Table (6): Comparison between the First four weeks and Second four weeks according to sodium levels (Na) mEq/L in Group II**

Cases	First four weeks				Second four weeks			
	Na 1	Na 2	Na 3	Na 4	Na 5	Na 6	Na 7	Na 8
1	136.0	134.0	137.0	137.0	136.0	135.0	138.0	139.0
2	138.0	139.0	136.0	140.0	138.0	137.0	136.0	136.0
3	136.0	137.0	136.0	136.0	135.0	133.0	136.0	137.0
4	135.0	136.0	137.0	136.0	135.0	136.0	137.0	137.0
5	146.0	149.0	152.0	155.0	149.0	148.0	149.0	144.0
6	136.0	134.0	137.0	136.0	137.0	138.0	137.0	136.0
7	146.0	147.0	146.0	143.0	142.0	143.0	146.0	143.0
8	137.0	136.0	137.0	136.0	137.0	136.0	137.0	136.0
9	136.0	139.0	146.0	150.0	155.0	149.0	148.0	147.0
10	135.0	137.0	138.0	136.0	135.0	136.0	137.0	134.0
11	139.0	140.0	145.0	150.0	145.0	146.0	143.0	142.0
12	139.0	134.0	136.0	137.0	134.0	139.0	137.0	136.0
13	136.0	135.0	136.0	137.0	137.0	135.0	136.0	139.0
14	136.0	137.0	136.0	137.0	136.0	137.0	136.0	137.0
15	136.0	137.0	136.0	137.0	136.0	137.0	136.0	137.0
16	142.0	143.0	143.0	140.0	141.0	142.0	142.0	141.0
17	149.0	150.0	148.0	146.0	149.0	145.0	144.0	143.0
18	141.0	142.0	138.0	136.0	139.0	141.0	143.0	135.0
19	131.0	136.0	139.0	138.0	134.0	136.0	135.0	136.0
20	138.0	134.0	136.0	135.0	137.0	137.0	136.0	136.0
21	136.0	137.0	138.0	136.0	137.0	136.0	138.0	136.0
22	137.0	136.0	139.0	141.0	142.0	139.0	138.0	140.0
23	136.0	134.0	136.0	139.0	138.0	136.0	137.0	139.0
24	137.0	136.0	139.0	142.0	142.0	137.0	139.0	134.0
25	137.0	136.0	138.0	135.0	136.0	139.0	142.0	140.0
26	139.0	150.0	155.0	144.0	145.0	142.0	144.0	142.0
27	145.0	144.0	150.0	141.0	142.0	143.0	143.0	142.0
28	138.0	139.0	135.0	140.0	137.0	136.0	139.0	140.0
29	136.0	137.0	139.0	136.0	135.0	134.0	132.0	133.0
30	137.0	134.0	137.0	137.0	136.0	135.0	138.0	139.0
<b>Mean</b>	<b>138.20</b>	<b>138.63</b>	<b>140.03</b>	<b>139.63</b>	<b>139.23</b>	<b>138.77</b>	<b>139.30</b>	<b>138.53</b>
<b>SD</b>	<b>3.88</b>	<b>4.90</b>	<b>5.44</b>	<b>5.0</b>	<b>4.28</b>	<b>5.09</b>	<b>4.20</b>	<b>4.11</b>
	<b>1<sup>st</sup> month</b>				<b>2<sup>nd</sup> month</b>			
<b>Min</b>	135.75				133.50			
<b>Max</b>	150.50				149.75			
<b>Mean</b>	139.12				138.96			
<b>SD</b>	4.28				3.94			
<b>Median</b>	136.63				137.0			
<b>Z<sub>1</sub></b>	0.686							
<b>p<sub>1</sub></b>	0.492							

Z<sub>1</sub>: Z for Wilcoxon signed ranks test

p<sub>1</sub>: p value for Wilcoxon signed ranks test for comparing between 1<sup>st</sup> and 2<sup>nd</sup> month

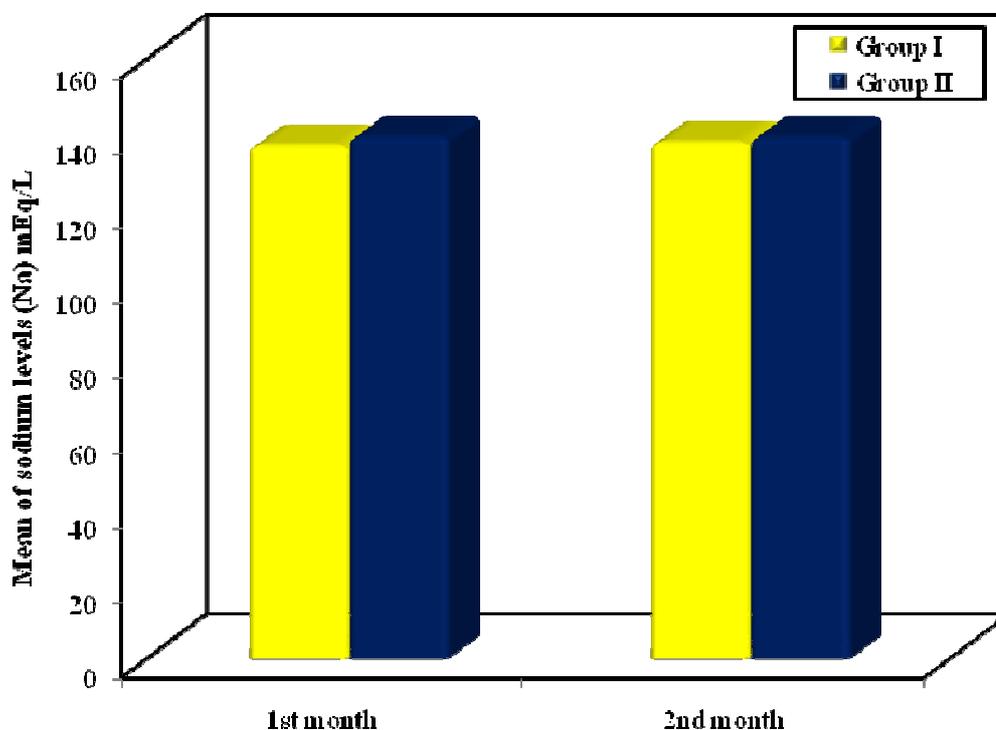
**Table (7): Comparison between the two studied groups in the 1st and 2nd month according to sodium levels (Na) mEq/L**

Sodium	Group I (n=30)	Group II (n=30)	Z	p
<b>1<sup>st</sup> month</b>				
Min. – Max.	131.50 - 145.75	135.75 - 150.50	2.603*	0.009*
Mean ± SD.	136.64 ± 2.77	139.12 ± 4.28		
Median	136.25	136.63		
<b>2<sup>nd</sup> month</b>				
Min. – Max.	134.75 - 144.75	133.50 - 149.75	1.348	01.178
Mean ± SD.	137.57 ± 2.37	138.96 ± 3.94		
Median	136.88	137.0		

Z: Z for Mann Whitney test

p: p value for Mann Whitney test for comparing between the two studied groups

\*: Statistically significant at  $p \leq 0.05$



**Figure (9): Comparison between the two studied groups in the 1<sup>st</sup> and 2<sup>nd</sup> month according to sodium levels (Na) mEq/L.**

**Table (8): Comparison between the First four weeks and Second four weeks according to Potassium levels (K) mEq/L in Group I**

Cases	First four weeks				Second four weeks			
	K 1	K 2	K 3	K 4	K 5	K 6	K 7	K 8
1	3.20	3.00	3.60	2.60	3.70	4.20	4.00	4.20
2	3.50	3.60	2.90	3.30	3.70	3.20	3.80	3.90
3	3.60	3.50	3.60	3.50	3.70	3.20	3.60	3.60
4	4.00	3.80	3.90	4.20	3.90	3.80	4.10	4.10
5	4.20	4.30	3.90	3.80	4.00	4.10	4.20	3.80
6	3.00	3.60	3.20	3.30	3.50	3.70	3.60	3.80
7	3.80	4.00	4.20	3.80	3.20	3.60	3.70	3.50
8	3.70	3.60	3.70	3.50	3.60	3.20	3.80	3.70
9	4.20	3.90	3.80	4.00	3.50	3.60	3.60	3.90
10	3.60	3.70	4.00	4.20	3.90	3.60	3.50	3.80
11	3.60	3.70	3.60	3.20	3.80	3.60	3.80	3.80
12	3.90	3.20	3.50	4.00	3.90	3.80	3.80	3.90
13	3.40	3.60	3.50	3.70	3.60	3.60	3.80	3.20
14	5.00	4.80	4.90	4.40	4.30	4.70	4.30	4.20
15	3.40	3.60	3.80	3.20	3.30	3.60	3.80	3.50
16	3.60	3.70	3.60	3.70	3.50	3.80	3.20	3.50
17	2.90	3.50	3.60	2.80	3.20	3.10	3.80	3.60
18	3.80	3.70	3.70	3.50	3.80	3.60	3.70	3.90
19	5.60	5.20	5.00	4.90	4.90	4.80	5.00	5.10
20	3.20	3.60	3.80	3.50	3.60	3.70	3.60	3.80
21	3.40	3.60	3.20	3.70	3.00	3.60	3.60	3.70
22	3.70	3.80	3.20	4.00	4.30	4.20	3.80	3.90
23	2.80	3.60	3.70	3.10	3.90	3.70	3.60	3.70
24	3.20	3.40	3.50	3.20	3.80	3.00	3.60	3.60
25	3.70	2.80	3.10	3.70	3.90	3.40	3.60	3.60
26	4.10	3.90	3.70	3.90	3.20	3.60	3.60	3.80
27	2.60	2.90	3.10	3.50	3.60	3.60	3.80	3.90
28	3.20	3.60	3.70	3.20	4.00	4.10	3.90	3.60
29	3.40	3.60	3.90	2.90	3.10	3.60	3.70	3.20
30	3.60	3.70	3.20	3.90	4.10	4.20	4.10	3.90
<b>Mean</b>	<b>3.63</b>	<b>3.68</b>	<b>3.67</b>	<b>3.61</b>	<b>3.72</b>	<b>3.72</b>	<b>3.80</b>	<b>3.79</b>
<b>SD</b>	<b>0.60</b>	<b>0.47</b>	<b>0.46</b>	<b>0.49</b>	<b>0.40</b>	<b>0.42</b>	<b>0.32</b>	<b>0.34</b>
	<b>1<sup>st</sup> month</b>				<b>2<sup>nd</sup> month</b>			
<b>Min</b>	3.03				3.40			
<b>Max</b>	5.18				4.95			
<b>Mean</b>	3.65				3.76			
<b>SD</b>	0.45				0.32			
<b>Median</b>	3.55				3.66			
<b>t1</b>	1.843							
<b>p1</b>	0.076							

t<sub>1</sub>: Paired t-test

p<sub>1</sub>: p value for Paired t-test for comparing between 1<sup>st</sup> and 2<sup>nd</sup> month

**Table (9): Comparison between the First four weeks and Second four weeks according to Potassium levels (K) mEq/L in Group II**

Cases	First four weeks				Second four weeks			
	K 1	K 2	K 3	K 4	K 5	K 6	K 7	K 8
1	3.60	3.70	2.90	3.40	3.60	3.60	3.90	3.20
2	3.20	3.40	3.90	4.00	3.70	3.80	3.70	3.70
3	3.40	3.70	7.20	3.40	3.60	3.60	3.90	3.70
4	3.60	3.70	3.80	3.70	3.60	3.60	3.80	3.90
5	2.90	2.80	2.90	3.60	3.70	3.20	3.10	3.60
6	4.20	4.30	4.20	4.00	4.10	3.90	3.80	3.90
7	2.40	2.90	3.10	3.20	3.40	3.80	3.40	3.20
8	3.70	3.60	3.80	3.60	3.70	3.80	3.60	3.70
9	3.40	3.60	3.70	2.90	3.60	3.90	3.40	3.60
10	3.60	3.70	3.60	3.70	3.70	3.60	3.70	3.90
11	3.70	3.60	3.90	3.90	3.80	4.00	3.80	3.90
12	4.20	4.30	3.60	3.70	3.90	3.70	3.60	3.90
13	3.20	3.40	3.60	3.70	3.90	3.60	3.70	3.60
14	4.20	4.10	4.10	3.90	3.60	3.80	3.90	3.70
15	3.60	3.70	3.60	3.60	3.70	3.80	3.80	3.70
16	3.60	3.70	3.60	3.80	3.70	3.60	3.80	3.90
17	2.90	3.20	3.40	3.60	3.50	3.70	3.40	3.60
18	3.80	3.90	2.40	3.10	3.40	3.60	3.70	3.60
19	3.40	3.20	3.50	3.80	3.20	3.60	3.70	3.80
20	3.90	3.20	3.80	3.40	3.40	3.60	3.70	3.60
21	3.40	3.70	3.80	3.60	3.90	3.60	3.70	3.60
22	3.60	3.70	4.20	3.90	3.70	3.80	3.60	3.60
23	3.60	3.70	3.20	4.10	3.90	4.20	3.80	3.60
24	3.40	4.20	4.10	3.90	3.80	3.80	3.90	3.70
25	3.40	3.20	2.90	3.90	2.60	3.10	3.50	3.20
26	3.70	3.90	3.60	3.70	3.80	3.90	3.80	3.80
27	3.70	3.90	3.80	3.20	3.60	3.70	3.40	3.60
28	4.20	4.30	3.90	3.80	3.90	4.00	4.10	3.90
29	3.60	3.70	2.80	2.90	3.10	3.50	3.60	3.70
30	3.60	3.70	2.90	3.40	3.60	3.60	3.90	3.80
<b>Mean</b>	<b>3.56</b>	<b>3.66</b>	<b>3.66</b>	<b>3.61</b>	<b>3.62</b>	<b>3.62</b>	<b>3.70</b>	<b>3.69</b>
<b>SD</b>	<b>0.40</b>	<b>0.38</b>	<b>0.81</b>	<b>0.32</b>	<b>0.33</b>	<b>0.29</b>	<b>0.22</b>	<b>0.21</b>
	<b>1<sup>st</sup> month</b>				<b>2<sup>nd</sup> month</b>			
<b>Min</b>	2.90				3.10			
<b>Max</b>	4.43				3.98			
<b>Mean</b>	3.62				3.67			
<b>SD</b>	0.33				0.17			
<b>Median</b>	3.64				3.70			
<b>t1</b>	1.114							
<b>p1</b>	0.274							

t<sub>1</sub>: Paired t-test

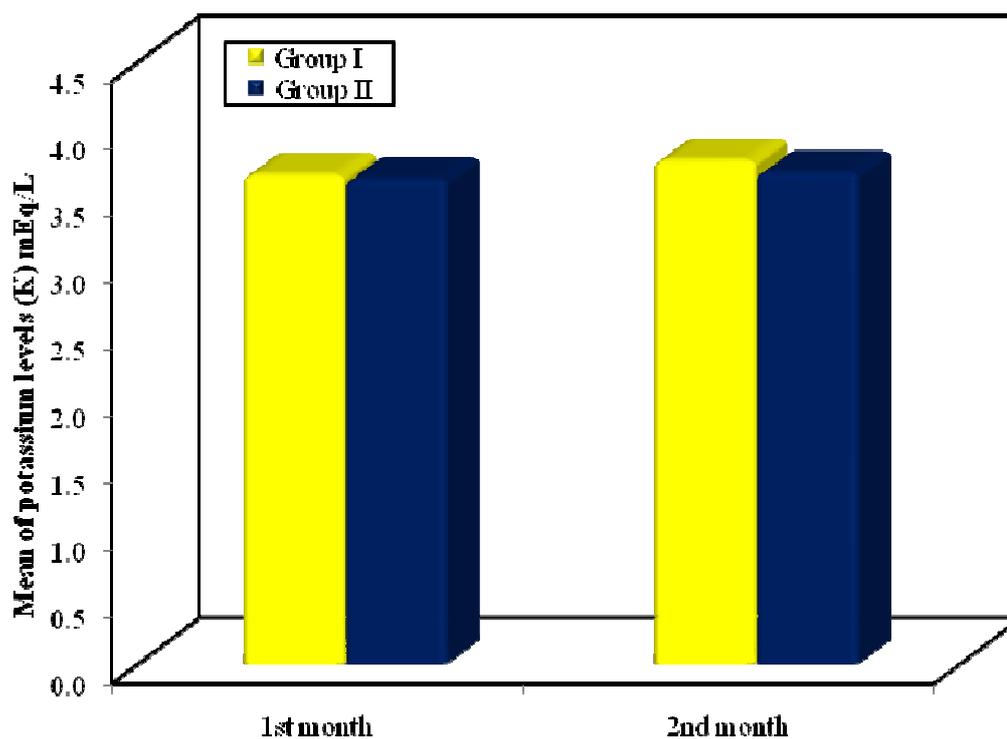
p<sub>1</sub>: p value for Paired t-test for comparing between 1<sup>st</sup> and 2<sup>nd</sup> month

**Table (10): Comparison between the two studied groups in the 1st and 2nd month according to Potassium levels (K) mEq/L**

Potassium	Group I (n=30)	Group II (n=30)	t	p
<b>1<sup>st</sup> month</b>				
Min. – Max.	3.03 - 5.18	2.90 - 4.43	0.255	0.800
Mean ± SD.	3.65 ± 0.45	3.62 ± 0.33		
Median	3.55	3.64		
<b>2<sup>nd</sup> month</b>				
Min. – Max.	3.40 - 4.95	3.10 - 3.98	1.260	0.214
Mean ± SD.	3.76 ± 0.32	3.67 ± 0.17		
Median	3.66	3.70		

t: Student t-test

p: p value for Student t-test for comparing between the two studied groups



**Figure (10): Comparison between the two studied groups in the 1<sup>st</sup> and 2<sup>nd</sup> month according to Potassium levels (K) mEq/L**

### 3. Comparison between the two studied groups according to chloride levels (Cl<sup>-</sup>) mEq/L

There was no statically significant difference between the patients in group I after one and two months of admission at all time of measurements ( $p=0.333$ ) (table 11) also there was no statistically significant difference in the group II after one and two months of admission at all time of measurements ( $p=0.057$ ) (table 11), but There was statically significant difference between group I and group II after one month of admission ( $p=0.002$ ) and no statically significant difference in the 2nd month ( $p=0.120$ ) (table 11, figure 11).

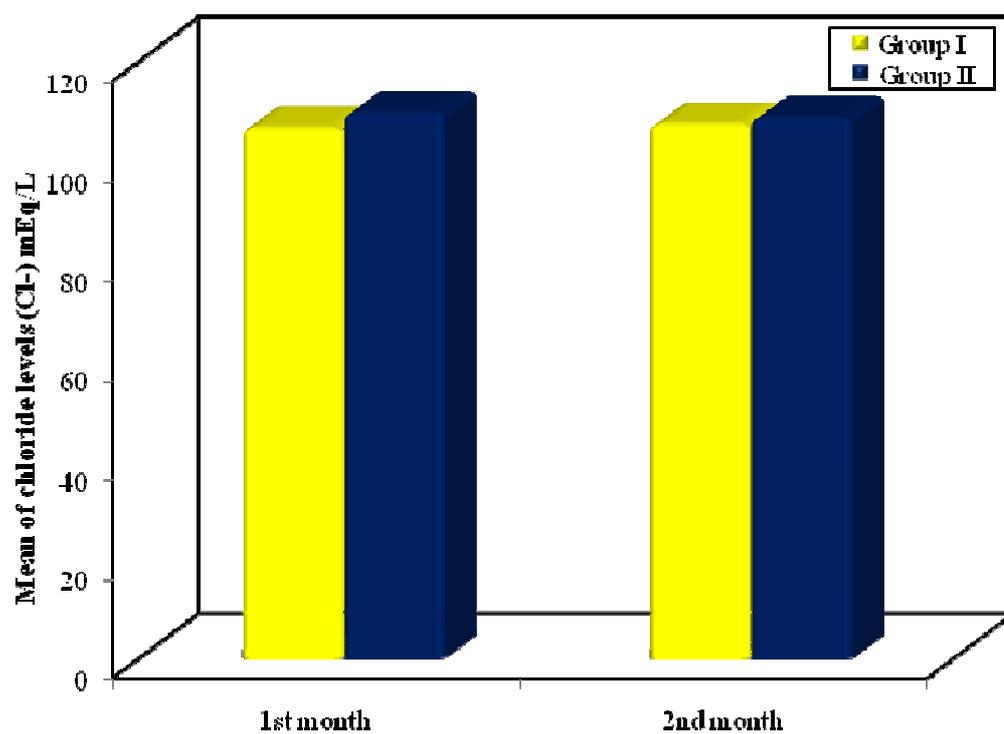
**Table (11): Comparison between the two studied groups in the 1st and 2nd month according to chloride levels (Cl<sup>-</sup>) mEq/L**

Chloride	Group I (n=30)	Group II (n=30)	Z	p
<b>1<sup>st</sup> month</b>				
Min. – Max.	98.0 - 113.50	96.75 - 113.50	3.057*	0.002*
Mean ± SD.	106.58 ± 4.80	109.60 ± 4.26		
Median	109.38	110.50		
<b>2<sup>nd</sup> month</b>				
Min. – Max.	96.50 - 113.25	98.0 - 114.25	1.554	0.120
Mean ± SD.	107.35 ± 3.78	108.67 ± 3.63		
Median	108.50	109.25		
<b>p</b>	0.333	0.057		

Z: Z for Mann Whitney test

p: p value for Mann Whitney test for comparing between the two studied groups

\*: Statistically significant at  $p \leq 0.05$



**Figure (11):** Comparison between the two studied groups in the 1<sup>st</sup> and 2<sup>nd</sup> month according to chloride levels (Cl-) mEq/L

**4. Comparison between the two studied groups according to bicarbonate levels (HCO<sub>3</sub><sup>-</sup>) mEq/L**

There was no statically significant difference between the patients in group I after one and two months of admission at all time of measurements (p=0.399) (table 12) also there was no statistically significant difference in the group II after one and two months of admission at all time of measurements(p=0.071) (table 13).

Compression between the patients in group I and group II after one month of admission (p=0.098) with no statically significant difference and statically significant difference in the 2nd month (p=0.012) (table 14, figure 12).

**5. Comparison between the two studied groups according to blood glucose level mg/dl**

There was no statically significant difference between the patients in group I after one and two months of admission at all time of measurements (p=0.285) (table 15)also there was no statistically significant difference in the group II after one and two months of admission at all time of measurements (p=0.586) (table 16).

In compression between the patients in group I and group II after one and two months of admission there was no statistically significant difference at all time of measurements p=0.784p=0.511 respectively (table 17, figure 13).

**Table (12): Comparison between the First four weeks and Second four weeks according to bicarbonate levels (HCO<sub>3</sub><sup>-</sup>) mEq/L in Group I**

Cases	First four weeks				Second four weeks			
	HCO <sub>3</sub> -1	HCO <sub>3</sub> -2	HCO <sub>3</sub> -3	HCO <sub>3</sub> -4	HCO <sub>3</sub> -5	HCO <sub>3</sub> -6	HCO <sub>3</sub> -7	HCO <sub>3</sub> -8
1	23.0	26.0	30.0	22.0	24.0	30.0	22.0	23.0
2	19.0	30.0	32.0	28.0	27.0	27.0	23.0	25.0
3	22.0	23.0	30.0	28.0	29.0	25.0	22.0	24.0
4	20.0	18.0	22.0	25.0	23.0	25.0	23.0	24.0
5	36.0	36.0	33.0	26.0	22.0	23.0	23.0	24.0
6	18.0	20.0	22.0	20.0	22.0	24.0	22.0	21.0
7	30.0	26.0	24.0	25.0	22.0	34.0	29.0	24.0
8	22.0	21.0	21.0	23.0	24.0	26.0	23.0	26.0
9	23.0	25.0	24.0	30.0	26.0	23.0	22.0	25.0
10	19.0	20.0	22.0	24.0	23.0	24.0	26.0	22.0
11	23.0	24.0	22.0	25.0	22.0	26.0	25.0	23.0
12	24.0	25.0	23.0	22.0	25.0	23.0	24.0	22.0
13	23.0	23.0	22.0	24.0	25.0	22.0	26.0	24.0
14	24.0	25.0	26.0	23.0	22.0	25.0	26.0	25.0
15	30.0	32.0	29.0	26.0	27.0	23.0	22.0	25.0
16	22.0	25.0	26.0	23.0	22.0	23.0	22.0	24.0
17	33.0	32.0	26.0	24.0	25.0	24.0	23.0	26.0
18	33.0	26.0	24.0	25.0	24.0	23.0	22.0	25.0
19	18.0	19.0	20.0	17.0	19.0	19.0	18.0	20.0
20	21.0	23.0	23.0	22.0	22.0	23.0	21.0	21.0
21	22.0	20.0	21.0	25.0	23.0	26.0	22.0	23.0
22	22.0	23.0	26.0	22.0	23.0	25.0	22.0	24.0
23	19.0	22.0	24.0	26.0	22.0	23.0	24.0	26.0
24	19.0	21.0	21.0	22.0	23.0	26.0	27.0	24.0
25	22.0	25.0	29.0	26.0	30.0	27.0	28.0	29.0
26	19.0	20.0	22.0	24.0	23.0	24.0	22.0	23.0
27	19.0	20.0	22.0	24.0	24.0	23.0	25.0	24.0
28	23.0	24.0	22.0	23.0	25.0	24.0	22.0	26.0
29	23.0	24.0	22.0	23.0	26.0	25.0	24.0	23.0
30	23.0	26.0	24.0	25.0	23.0	25.0	24.0	23.0
<b>Mean</b>	<b>23.13</b>	<b>24.13</b>	<b>24.47</b>	<b>24.07</b>	<b>23.90</b>	<b>24.67</b>	<b>23.47</b>	<b>23.93</b>
<b>SD</b>	<b>4.67</b>	<b>4.13</b>	<b>3.51</b>	<b>2.49</b>	<b>2.31</b>	<b>2.63</b>	<b>2.27</b>	<b>1.80</b>
	<b>1<sup>st</sup> month</b>				<b>2<sup>nd</sup> month</b>			
<b>Min</b>	18.50				19.0			
<b>Max</b>	32.75				28.50			
<b>Mean</b>	23.95				23.99			
<b>SD</b>	3.03				1.61			
<b>Median</b>	23.38				24.0			
<b>Z<sub>1</sub></b>	0.843							
<b>p<sub>1</sub></b>	0.399							

Z<sub>1</sub>: Z for Wilcoxon signed ranks test

p<sub>1</sub>: p value for Wilcoxon signed ranks test for comparing between 1<sup>st</sup> and 2<sup>nd</sup> month

**Table (13): Comparison between the First four weeks and Second four weeks according to bicarbonate levels (HCO<sub>3</sub><sup>-</sup>) mEq/L in Group II.**

Cases	First four weeks				Second four weeks			
	HCO <sub>3</sub> -1	HCO <sub>3</sub> -2	HCO <sub>3</sub> -3	HCO <sub>3</sub> -4	HCO <sub>3</sub> -5	HCO <sub>3</sub> -6	HCO <sub>3</sub> -7	HCO <sub>3</sub> -8
1	22.0	23.0	22.0	24.0	23.0	22.0	21.0	23.0
2	19.0	20.0	24.0	23.0	22.0	26.0	27.0	24.0
3	22.0	23.0	24.0	26.0	24.0	23.0	22.0	23.0
4	23.0	24.0	26.0	22.0	24.0	23.0	23.0	24.0
5	20.0	19.0	20.0	22.0	24.0	21.0	22.0	24.0
6	116.0	112.0	113.0	111.0	112.0	109.0	106.0	107.0
7	19.0	18.0	19.0	19.0	20.0	24.0	23.0	22.0
8	23.0	24.0	22.0	23.0	24.0	25.0	22.0	23.0
9	23.0	19.0	20.0	21.0	24.0	24.0	23.0	24.0
10	22.0	23.0	24.0	23.0	25.0	22.0	23.0	22.0
11	18.0	19.0	23.0	26.0	25.0	24.0	22.0	23.0
12	22.0	24.0	23.0	24.0	25.0	23.0	24.0	23.0
13	23.0	24.0	22.0	23.0	24.0	26.0	24.0	24.0
14	24.0	23.0	26.0	24.0	25.0	26.0	24.0	23.0
15	23.0	24.0	23.0	22.0	25.0	26.0	24.0	24.0
16	22.0	24.0	23.0	24.0	23.0	22.0	25.0	24.0
17	20.0	21.0	20.0	18.0	22.0	23.0	24.0	23.0
18	23.0	24.0	21.0	22.0	23.0	20.0	21.0	22.0
19	24.0	23.0	23.0	26.0	21.0	22.0	23.0	24.0
20	23.0	24.0	26.0	28.0	25.0	24.0	25.0	2.0
21	18.0	19.0	23.0	22.0	23.0	24.0	23.0	24.0
22	23.0	24.0	22.0	23.0	25.0	26.0	25.0	24.0
23	23.0	24.0	22.0	23.0	24.0	23.0	24.0	23.0
24	19.0	22.0	23.0	20.0	24.0	22.0	23.0	24.0
25	23.0	26.0	22.0	26.0	25.0	24.0	23.0	21.0
26	22.0	23.0	24.0	23.0	23.0	24.0	23.0	24.0
27	20.0	21.0	22.0	24.0	23.0	22.0	24.0	23.0
28	23.0	24.0	26.0	22.0	21.0	22.0	23.0	24.0
29	18.0	21.0	22.0	23.0	22.0	24.0	23.0	22.0
30	22.0	23.0	22.0	24.0	23.0	22.0	21.0	23.0
<b>Mean</b>	<b>24.73</b>	<b>25.40</b>	<b>25.73</b>	<b>26.03</b>	<b>26.43</b>	<b>26.27</b>	<b>26.0</b>	<b>25.33</b>
<b>SD</b>	<b>17.34</b>	<b>16.48</b>	<b>16.58</b>	<b>16.18</b>	<b>16.22</b>	<b>15.71</b>	<b>15.17</b>	<b>15.93</b>
	<b>1<sup>st</sup> month</b>				<b>2<sup>nd</sup> month</b>			
<b>Min</b>	18.75				19.0			
<b>Max</b>	113.0				108.50			
<b>Mean</b>	25.48				26.01			
<b>SD</b>	16.60				15.62			
<b>Median</b>	23.0				23.38			
<b>Z1</b>	1.808							
<b>p1</b>	0.071							

Z<sub>1</sub>: Z for Wilcoxon signed ranks test

p<sub>1</sub>: p value for Wilcoxon signed ranks test for comparing between 1<sup>st</sup> and 2<sup>nd</sup> month

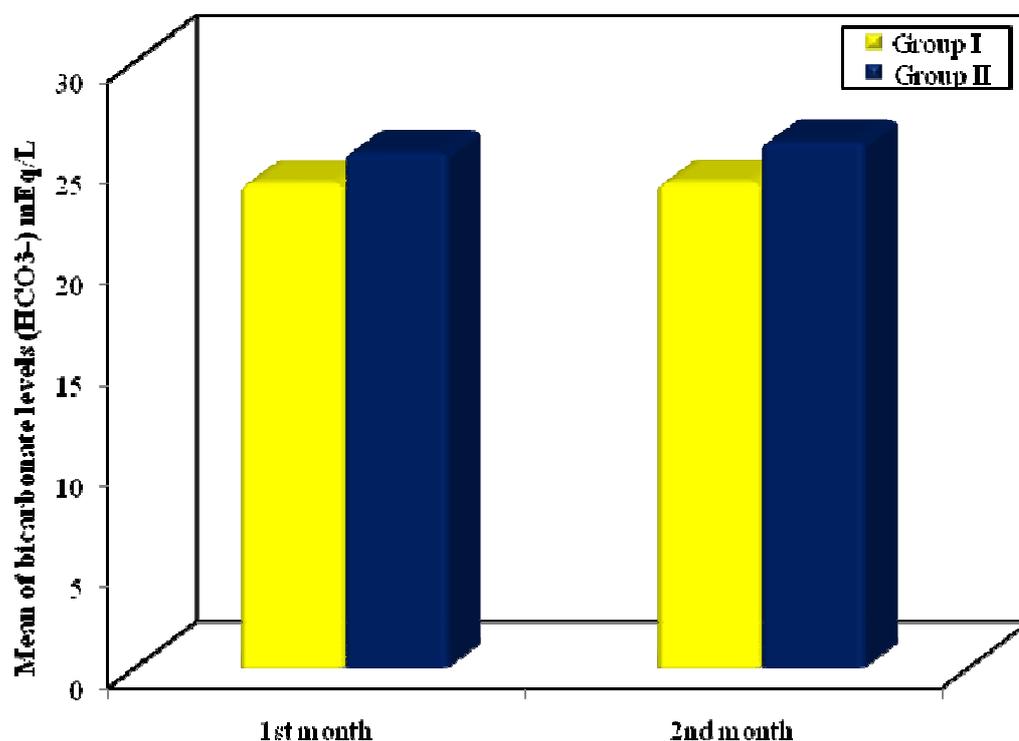
**Table (14): Comparison between the two studied groups in the 1st and 2nd month according to bicarbonate levels (HCO<sub>3</sub><sup>-</sup>) mEq/L.**

Bicarbonate	Group I (n=30)	Group II (n=30)	Z	p
<b>1<sup>st</sup> month</b>				
Min. – Max.	18.50 - 32.75	18.75 - 113.0	1.653	0.098
Mean ± SD.	23.95 ± 3.03	25.48 ± 16.60		
Median	23.38	23.0		
<b>2<sup>nd</sup> month</b>				
Min. – Max.	19.0 - 28.50	19.0 - 108.50	2.511*	0.012*
Mean ± SD.	23.99 ± 1.61	26.01 ± 15.62		
Median	24.0	23.38		

Z: Z for Mann Whitney test

p: p value for Mann Whitney test for comparing between the two studied groups

\*: Statistically significant at  $p \leq 0.05$



**Figure (12): Comparison between the two studied groups in the 1<sup>st</sup> and 2<sup>nd</sup> month according to bicarbonate levels (HCO<sub>3</sub><sup>-</sup>) mEq/L.**

**Table (15): Comparison between the First four weeks and Second four weeks according to blood glucose levels (mg/dl) in Group I.**

Cases	First four weeks				Second four weeks			
	glucose1	glucose2	glucose3	glucose4	glucose5	glucose6	glucose7	glucose8
1	120	126	98	111	118	120	90	100
2	170	201	198	190	188	210	206	198
3	114	203	89	70	79	82	80	70
4	215	201	180	119	177	156	120	133
5	80	95	101	95	74	88	95	96
6	215	223	233	180	211	213	220	200
7	300	280	250	255	230	233	200	198
8	75	79	80	95	93	101	88	79
9	114	121	150	133	108	170	119	122
10	264	280	216	222	280	265	210	222
11	110	121	235	122	118	120	117	102
12	95	98	85	95	96	92	90	89
13	98	108	115	95	120	130	138	102
14	212	215	218	209	223	250	210	213
15	110	122	113	95	99	120	118	113
16	78	80	82	90	75	82	99	101
17	105	100	180	122	170	175	160	143
18	102	108	216	170	160	164	133	120
19	320	289	282	250	266	220	222	200
20	280	229	250	233	218	310	270	216
21	110	130	145	130	133	134	136	134
22	210	230	180	137	210	220	199	210
23	210	212	222	180	188	190	210	212
24	230	214	213	215	300	310	219	212
25	179	199	180	186	177	140	156	162
26	316	314	280	290	260	266	216	223
27	102	113	95	96	97	96	80	76
28	95	110	126	117	110	114	96	89
29	110	122	150	136	132	122	109	119
30	116	107	120	119	118	117	124	101
<b>Mean</b>	<b>161.83</b>	<b>167.67</b>	<b>169.40</b>	<b>151.90</b>	<b>160.93</b>	<b>167.00</b>	<b>151.00</b>	<b>145.17</b>
<b>SD</b>	<b>77.44</b>	<b>69.96</b>	<b>63.04</b>	<b>58.89</b>	<b>65.88</b>	<b>68.16</b>	<b>55.36</b>	<b>53.49</b>
	<b>1<sup>st</sup> month</b>				<b>2<sup>nd</sup> month</b>			
<b>Min</b>	82.25				77.75			
<b>Max</b>	300.00				260.25			
<b>Mean</b>	162.70				156.03			
<b>SD</b>	64.01				59.07			
<b>Median</b>	138.25				139.25			
<b>Z1</b>	1.070							
<b>p1</b>	0.285							

Z<sub>1</sub>: Z for Wilcoxon signed ranks test

p<sub>1</sub>: p value for Wilcoxon signed ranks test for comparing between 1<sup>st</sup> and 2<sup>nd</sup> month

**Table (16): Comparison between the First four weeks and Second four weeks according to blood glucose levels (mg/dl) in Group II**

Cases	First four weeks				Second four weeks			
	glucose 1	glucose 2	glucose 3	glucose 4	glucose 5	glucose 6	glucose 7	glucose 8
1	88.0	90.0	85.0	95.0	90.0	92.0	93.0	86.0
2	182.0	200.0	210.0	199.0	240.0	198.0	199.0	210.0
3	204.0	209.0	204.0	216.0	214.0	198.0	190.0	199.0
4	28.0	25.0	22.0	96.0	96.0	97.0	97.0	92.0
5	301.0	290.0	250.0	260.0	236.0	201.0	260.0	240.0
6	124.0	194.0	201.0	316.0	204.0	209.0	216.0	214.0
7	320.0	304.0	290.0	240.0	310.0	314.0	312.0	314.0
8	85.0	86.0	87.0	85.0	90.0	96.0	95.0	90.0
9	216.0	215.0	219.0	300.0	310.0	216.0	214.0	215.0
10	92.0	94.0	80.0	85.0	92.0	101.0	104.0	98.0
11	216.0	244.0	230.0	198.0	210.0	220.0	230.0	244.0
12	102.0	106.0	78.0	90.0	95.0	85.0	86.0	89.0
13	95.0	96.0	80.0	77.0	76.0	90.0	95.0	85.0
14	94.0	96.0	92.0	80.0	110.0	121.0	96.0	110.0
15	116.0	109.0	140.0	160.0	143.0	116.0	125.0	163.0
16	110.0	115.0	180.0	176.0	144.0	136.0	183.0	194.0
17	310.0	216.0	317.0	342.0	260.0	244.0	210.0	232.0
18	330.0	280.0	275.0	266.0	263.0	275.0	216.0	219.0
19	102.0	110.0	140.0	135.0	134.0	135.0	136.0	139.0
20	110.0	108.0	107.0	199.0	140.0	163.0	174.0	184.0
21	210.0	188.0	185.0	186.0	183.0	143.0	126.0	132.0
22	180.0	195.0	210.0	215.0	200.0	201.0	284.0	245.0
23	110.0	108.0	120.0	182.0	132.0	142.0	145.0	112.0
24	114.0	132.0	140.0	136.0	146.0	135.0	152.0	144.0
25	310.0	305.0	280.0	216.0	340.0	315.0	224.0	235.0
26	180.0	177.0	167.0	170.0	177.0	165.0	140.0	145.0
27	214.0	216.0	180.0	119.0	170.0	166.0	170.0	170.0
28	198.0	190.0	192.0	201.0	180.0	195.0	170.0	166.0
29	120.0	110.0	132.0	114.0	112.0	90.0	95.0	102.0
30	88.0	90.0	85.0	95.0	90.0	92.0	93.0	86.0
<b>Mean</b>	<b>164.97</b>	<b>163.27</b>	<b>165.93</b>	<b>174.97</b>	<b>172.90</b>	<b>165.03</b>	<b>164.33</b>	<b>165.13</b>
<b>SD</b>	<b>83.62</b>	<b>74.79</b>	<b>74.71</b>	<b>74.73</b>	<b>73.71</b>	<b>65.93</b>	<b>62.68</b>	<b>62.86</b>
	<b>1<sup>st</sup> month</b>				<b>2<sup>nd</sup> month</b>			
<b>Min</b>	42.75				86.50			
<b>Max</b>	296.25				312.50			
<b>Mean</b>	167.28				166.85			
<b>SD</b>	72.69				63.92			
<b>Median</b>	159.38				160.50			
<b>Z<sub>1</sub></b>	0.545							
<b>p<sub>1</sub></b>	0.586							

Z<sub>1</sub>: Z for Wilcoxon signed ranks test

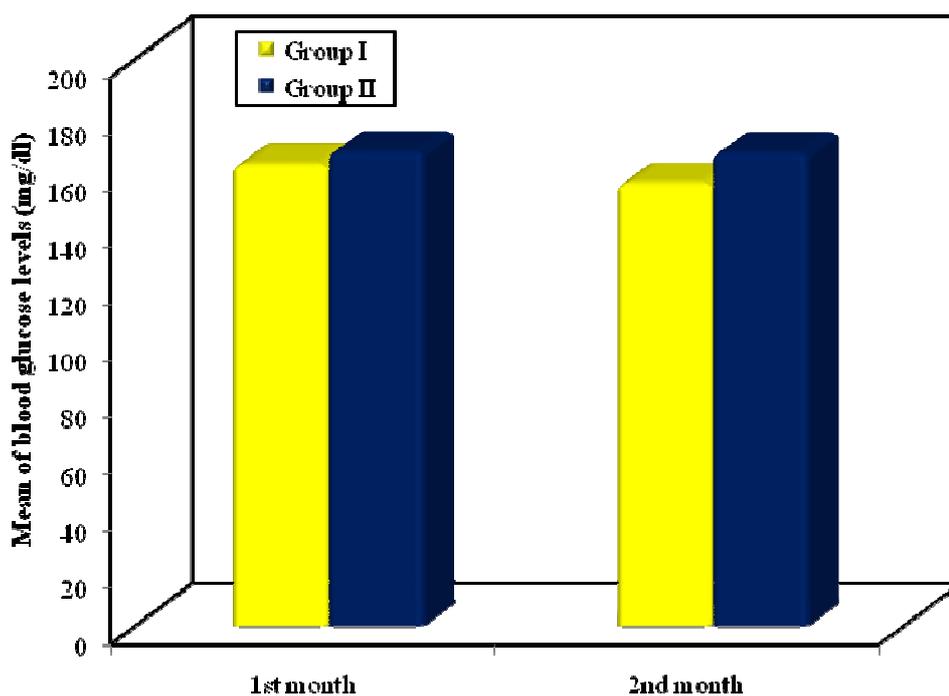
p<sub>1</sub>: p value for Wilcoxon signed ranks test for comparing between 1<sup>st</sup> and 2<sup>nd</sup> month

**Table (17): Comparison between the two studied groups in the 1st and 2nd month according to blood glucose levels (mg/dl)**

Blood glucose	Group I (n=30)	Group II (n=30)	Z	p
<b>1<sup>st</sup> month</b>				
Min. – Max.	82.25 – 300.0	42.75 – 296.25	0.274	0.784
Mean ± SD.	162.70 ± 64.01	167.28 ± 72.69		
Median	138.25	159.38		
<b>2<sup>nd</sup> month</b>				
Min. – Max.	77.75 – 260.25	86.50 – 312.50	0.658	0.511
Mean ± SD.	156.03 ± 59.07	166.85 ± 63.92		
Median	139.25	160.50		

Z: Z for Mann Whitney test

p: p value for Mann Whitney test for comparing between the two studied groups



**Figure (13): Comparison between the two studied groups in the 1<sup>st</sup> and 2<sup>nd</sup> month according to blood glucose levels (mg/dl).**

**5. Comparison between the two studied groups according to blood urea levels (mg/dl).**

There was no statically significant difference between the patients in group I after one and two months of admission at all time of measurements  $p=0.078$ (table 18) but there was statistically significant difference between the patients in group II after one and two months of admission  $p<0.001$ (table 19).

There was no statically significant difference between the patients in group I and group II after one and two months of admission  $p=0.647$  $p=0.923$  respectively (table 20, figure 14).

**6. Comparison between the studied groups according to creatinine levels (mg/dl).**

There was no statically significant difference between the patients in group I after one and two months of admission at all time of measurements (table 21) also in the group II after one and two months of admission at all time of measurements(table 22)  $p=0.201$  $p=0.982$  respectively.

There was no statically significant difference between the patients in group I and group II after one month and two months of admission at all time of measurements  $p=0.813$   $p=0.734$  respectively (table 23, figure 15).

**Table (18): Comparison between the First four weeks and Second four weeks according to blood urea levels (mg/dl) in Group I.**

Cases	First four weeks				Second four weeks			
	Urea 1	Urea 2	Urea 3	Urea 4	Urea 5	Urea 6	Urea 7	Urea 8
1	20.0	22.0	10.0	15.0	20.0	22.0	24.0	23.0
2	40.0	39.0	39.0	37.0	36.0	30.0	35.0	33.0
3	22.0	22.0	29.0	23.0	22.0	24.0	21.0	20.0
4	33.0	40.0	38.0	44.0	40.0	41.0	39.0	38.0
5	14.0	20.0	19.0	18.0	17.0	19.0	20.0	21.0
6	55.0	56.0	56.0	50.0	49.0	45.0	46.0	48.0
7	60.0	55.0	62.0	40.0	45.0	50.0	33.0	39.0
8	25.0	26.0	30.0	32.0	29.0	28.0	31.0	32.0
9	24.0	30.0	27.0	25.0	20.0	22.0	23.0	22.0
10	60.0	65.0	70.0	63.0	60.0	66.0	70.0	69.0
11	19.0	20.0	19.0	22.0	25.0	20.0	23.0	20.0
12	23.0	22.0	26.0	29.0	25.0	23.0	22.0	25.0
13	32.0	33.0	29.0	25.0	31.0	29.0	33.0	26.0
14	10.0	12.0	9.0	16.0	17.0	18.0	13.0	15.0
15	33.0	37.0	40.0	39.0	34.0	36.0	32.0	30.0
16	30.0	28.0	26.0	32.0	24.0	23.0	22.0	21.0
17	28.0	26.0	29.0	22.0	25.0	22.0	23.0	24.0
18	26.0	27.0	28.0	22.0	20.0	26.0	23.0	24.0
19	85.0	87.0	70.0	75.0	60.0	66.0	66.0	62.0
20	44.0	46.0	43.0	44.0	46.0	47.0	43.0	46.0
21	55.0	56.0	50.0	56.0	53.0	56.0	55.0	54.0
22	37.0	36.0	37.0	34.0	40.0	41.0	39.0	38.0
23	36.0	38.0	39.0	35.0	36.0	37.0	36.0	37.0
24	64.0	50.0	55.0	69.0	60.0	59.0	59.0	55.0
25	40.0	38.0	34.0	36.0	37.0	39.0	40.0	40.0
26	60.0	62.0	61.0	53.0	58.0	50.0	52.0	42.0
27	19.0	18.0	17.0	20.0	21.0	19.0	18.0	20.0
28	22.0	23.0	24.0	21.0	20.0	19.0	18.0	25.0
29	34.0	36.0	37.0	36.0	37.0	32.0	31.0	24.0
30	16.0	19.0	20.0	22.0	21.0	20.0	18.0	19.0
<b>Mean</b>	<b>35.53</b>	<b>36.30</b>	<b>35.77</b>	<b>35.17</b>	<b>34.27</b>	<b>34.30</b>	<b>33.60</b>	<b>33.07</b>
<b>SD</b>	<b>17.80</b>	<b>17.07</b>	<b>16.54</b>	<b>15.85</b>	<b>14.11</b>	<b>14.78</b>	<b>14.96</b>	<b>13.96</b>
	<b>1<sup>st</sup> month</b>				<b>2<sup>nd</sup> month</b>			
<b>Min</b>	11.75				15.75			
<b>Max</b>	79.25				66.25			
<b>Mean</b>	35.69				33.81			
<b>SD</b>	16.47				14.25			
<b>Median</b>	32.75				30.50			
<b>Z<sub>1</sub></b>	1.763							
<b>p<sub>1</sub></b>	0.078							

Z<sub>1</sub>: Z for Wilcoxon signed ranks test

p<sub>1</sub>: p value for Wilcoxon signed ranks test for comparing between 1<sup>st</sup> and 2<sup>nd</sup> month

**Table (19): Comparison between the First four weeks and Second four weeks according to blood urea levels (mg/dl) in Group II.**

Cases	First four weeks				Second four weeks			
	Urea 1	Urea 2	Urea 3	Urea 4	Urea 5	Urea 6	Urea 7	Urea 8
1	22.0	23.0	24.0	23.0	25.0	20.0	22.0	21.0
2	87.0	60.0	55.0	56.0	57.0	56.0	50.0	49.0
3	22.0	23.0	24.0	25.0	23.0	22.0	21.0	23.0
4	25.0	26.0	24.0	26.0	23.0	24.0	26.0	24.0
5	60.0	62.0	54.0	55.0	53.0	56.0	52.0	51.0
6	35.0	36.0	37.0	34.0	32.0	33.0	34.0	36.0
7	62.0	54.0	55.0	56.0	53.0	52.0	54.0	56.0
8	22.0	23.0	22.0	24.0	22.0	23.0	25.0	23.0
9	66.0	65.0	52.0	53.0	55.0	49.0	50.0	52.0
10	14.0	14.0	13.0	15.0	14.0	13.0	15.0	16.0
11	50.0	51.0	53.0	49.0	46.0	50.0	55.0	52.0
12	26.0	27.0	25.0	23.0	24.0	22.0	24.0	26.0
13	20.0	22.0	23.0	21.0	23.0	21.0	24.0	22.0
14	32.0	42.0	36.0	29.0	28.0	27.0	28.0	26.0
15	23.0	22.0	24.0	23.0	24.0	24.0	22.0	23.0
16	42.0	36.0	33.0	32.0	31.0	29.0	26.0	24.0
17	66.0	67.0	60.0	68.0	62.0	55.0	54.0	52.0
18	43.0	45.0	43.0	45.0	46.0	42.0	43.0	45.0
19	24.0	22.0	25.0	23.0	24.0	25.0	26.0	22.0
20	25.0	22.0	24.0	26.0	27.0	23.0	24.0	26.0
21	24.0	23.0	24.0	26.0	24.0	22.0	24.0	23.0
22	31.0	32.0	35.0	28.0	29.0	28.0	25.0	26.0
23	35.0	28.0	26.0	29.0	27.0	28.0	30.0	29.0
24	26.0	27.0	26.0	23.0	24.0	24.0	23.0	25.0
25	44.0	45.0	37.0	36.0	36.0	39.0	37.0	36.0
26	22.0	23.0	23.0	26.0	27.0	24.0	24.0	23.0
27	62.0	62.0	58.0	56.0	57.0	56.0	54.0	52.0
28	26.0	27.0	25.0	24.0	26.0	23.0	24.0	25.0
29	22.0	20.0	21.0	19.0	20.0	22.0	22.0	21.0
30	22.0	23.0	24.0	23.0	25.0	20.0	22.0	21.0
<b>Mean</b>	<b>36.0</b>	<b>35.07</b>	<b>33.50</b>	<b>33.20</b>	<b>32.90</b>	<b>31.73</b>	<b>32.00</b>	<b>31.67</b>
<b>SD</b>	<b>18.22</b>	<b>15.99</b>	<b>13.62</b>	<b>14.20</b>	<b>13.53</b>	<b>13.39</b>	<b>12.70</b>	<b>12.63</b>
	<b>1<sup>st</sup> month</b>				<b>2<sup>nd</sup> month</b>			
<b>Min</b>	14.0				14.50			
<b>Max</b>	65.25				55.75			
<b>Mean</b>	34.44				32.08			
<b>SD</b>	15.27				12.95			
<b>Median</b>	25.50				24.75			
<b>Z1</b>	3.677*							
<b>p1</b>	<0.001*							

Z<sub>1</sub>: Z for Wilcoxon signed ranks test

p<sub>1</sub>: p value for Wilcoxon signed ranks test for comparing between 1<sup>st</sup> and 2<sup>nd</sup> month

\*: Statistically significant at p ≤ 0.05

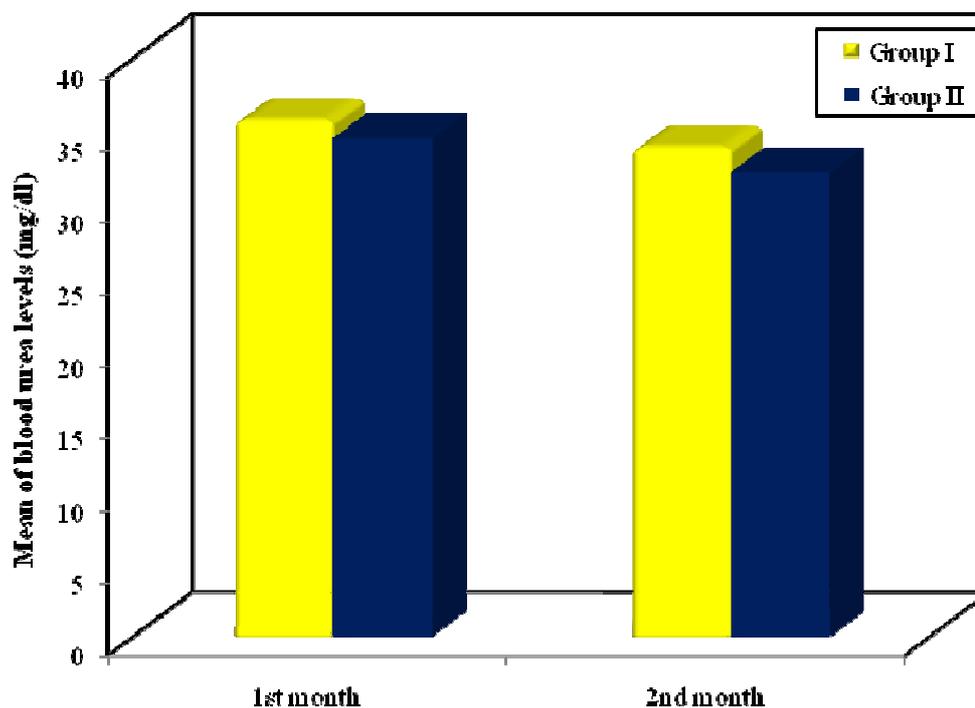
**Table (20): Comparison between the two studied groups in the 1st and 2nd month according to blood urea levels (mg/dl)**

Blood urea	Group I (n=30)	Group II (n=30)	Z	p
<b>1<sup>st</sup> month</b>				
Min. – Max.	11.75 – 79.25	14.0 – 65.25	0.458	0.647
Mean ± SD.	35.69 ± 16.47	34.44 ± 15.27		
Median	32.75	25.50		
<b>2<sup>nd</sup> month</b>				
Min. – Max.	15.75 – 66.25	14.50 – 55.75	0.096	0.923
Mean ± SD.	33.81 ± 14.25	32.08 ± 12.95		
Median	30.50	24.75		

Z: Z for Mann Whitney test

p: p value for Mann Whitney test for comparing between the two studied groups

\*: Statistically significant at  $p \leq 0.05$



**Figure (14): Comparison between the two studied groups in the 1<sup>st</sup> and 2<sup>nd</sup> month according to blood urea levels (mg/dl).**

**Table (21): Comparison between the First four weeks and Second four weeks according to creatinine levels (mg/dl) in Group I.**

Cases	First four weeks				Second four weeks			
	Creatinine 1	Creatinine 2	Creatinine 3	Creatinine 4	Creatinine 5	Creatinine 6	Creatinine 7	Creatinine 8
1	1.3	1.0	0.9	0.8	0.9	1.1	0.8	0.8
2	108.0	102.0	105.0	102.0	103.0	101.0	0.9	0.9
3	0.5	0.6	0.8	0.6	0.8	0.7	0.6	0.6
4	1.2	1.1	1.2	1.1	1.1	1.0	1.1	1.0
5	0.8	0.9	1.0	0.5	0.7	0.8	0.7	0.9
6	1.9	2.0	2.2	2.0	1.8	1.9	1.9	2.0
7	1.6	1.2	1.3	0.9	1.0	1.2	1.4	1.2
8	0.5	0.6	0.8	0.5	0.7	0.8	0.5	0.8
9	0.9	1.2	1.2	1.0	0.9	0.9	0.8	0.9
10	1.9	2.2	2.3	2.0	1.9	2.0	2.2	2.1
11	0.6	0.8	0.8	0.7	0.9	0.7	0.9	0.8
12	0.8	0.6	0.9	0.9	0.7	0.6	0.8	0.9
13	0.9	0.9	0.7	0.8	1.1	0.9	0.9	0.9
14	0.6	0.9	0.8	1.1	0.9	0.8	0.7	0.9
15	1.2	1.3	1.3	0.9	0.8	1.1	1.2	1.0
16	0.8	0.7	0.4	0.8	0.6	0.7	0.8	0.7
17	0.9	0.8	0.7	0.8	0.9	0.6	0.8	0.9
18	0.9	1.0	1.1	0.9	0.8	1.0	0.9	0.8
19	3.2	3.8	4.0	3.6	3.2	3.1	3.2	3.3
20	1.6	1.7	1.6	1.8	1.6	1.8	1.7	1.8
21	1.2	1.3	1.2	0.9	0.9	1.0	1.1	1.1
22	0.9	1.0	1.1	0.9	1.2	1.3	1.4	1.3
23	1.2	1.2	1.1	1.3	0.9	1.1	1.2	1.2
24	1.3	1.2	1.4	1.2	1.3	1.4	1.4	1.3
25	1.1	1.2	0.9	0.8	0.9	1.1	1.2	0.9
26	1.7	1.6	1.6	1.5	1.5	1.4	1.5	1.3
27	0.8	0.9	0.9	0.7	1.1	1.2	1.1	1.1
28	1.1	1.2	1.3	0.9	0.9	1.0	1.1	1.2
29	1.1	1.2	0.9	0.8	1.1	1.1	0.9	0.8
30	0.7	0.8	0.9	0.9	1.0	1.1	0.9	0.8
<b>Mean</b>	<b>4.71</b>	<b>4.56</b>	<b>4.68</b>	<b>4.45</b>	<b>4.50</b>	<b>4.48</b>	<b>1.15</b>	<b>1.14</b>
<b>SD</b>	<b>19.52</b>	<b>18.41</b>	<b>18.96</b>	<b>18.43</b>	<b>18.61</b>	<b>18.24</b>	<b>0.55</b>	<b>0.54</b>
	<b>1<sup>st</sup> month</b>				<b>2<sup>nd</sup> month</b>			
<b>Min</b>	0.60				0.68			
<b>Max</b>	104.25				51.45			
<b>Mean</b>	4.60				2.82			
<b>SD</b>	18.83				9.20			
<b>Median</b>	1.00				1.03			
<b>Z<sub>1</sub></b>	1.279							
<b>p<sub>1</sub></b>	0.201							

Z<sub>1</sub>: Z for Wilcoxon signed ranks test

p<sub>1</sub>: p value for Wilcoxon signed ranks test for comparing between 1<sup>st</sup> and 2<sup>nd</sup> month

**Table (22): Comparison between the First four weeks and Second four weeks according to creatinine levels (mg/dl) in Group II.**

Cases	First four weeks				Second four weeks			
	Creatinine 1	Creatinine 2	Creatinine 3	Creatinine 4	Creatinine 5	Creatinine 6	Creatinine 7	Creatinine 8
1	0.7	0.9	0.8	0.9	1.0	1.1	0.9	0.8
2	1.6	1.3	1.2	1.4	1.3	1.2	1.4	1.3
3	1.1	0.9	1.2	0.8	0.9	1.1	1.2	1.1
4	0.9	0.8	0.8	0.9	0.8	0.7	0.9	0.9
5	1.7	1.6	1.4	1.4	1.4	1.5	1.4	1.4
6	0.9	1.2	1.1	0.9	1.3	1.2	1.1	1.2
7	1.6	1.4	1.4	1.3	1.7	1.6	1.6	1.4
8	0.8	0.7	0.6	0.9	0.7	0.8	0.8	0.7
9	1.6	1.6	1.5	1.5	1.5	1.5	16.0	1.4
10	0.7	0.6	0.8	0.7	0.6	0.6	0.6	0.8
11	1.5	1.6	1.6	1.5	1.5	1.4	1.5	1.6
12	0.8	0.7	0.9	0.9	0.8	1.1	0.8	0.9
13	0.8	0.9	0.9	0.8	0.9	0.7	0.8	0.9
14	1.3	1.4	1.3	1.2	0.9	0.9	0.8	0.9
15	0.9	0.8	1.1	1.1	1.2	1.3	1.0	1.1
16	0.8	0.9	0.6	0.7	0.8	0.7	0.9	0.8
17	1.7	1.6	1.8	1.8	1.7	1.5	1.6	1.3
18	1.3	1.6	1.5	1.6	1.6	1.5	1.6	1.5
19	0.9	0.9	1.0	1.1	0.9	0.8	0.8	0.9
20	0.9	0.8	1.1	1.2	1.1	0.9	0.8	0.9
21	0.9	1.1	1.1	1.2	0.8	0.7	0.9	1.0
22	1.4	1.5	1.5	1.3	1.2	1.4	1.3	0.9
23	1.1	1.2	0.9	0.9	1.0	0.9	1.0	0.8
24	0.9	0.9	0.8	0.9	0.9	1.0	1.1	0.9
25	1.1	1.4	1.2	1.1	1.2	1.3	1.4	1.2
26	1.1	0.9	0.8	1.1	1.0	0.9	0.8	0.9
27	1.6	1.7	1.4	1.4	1.3	1.5	1.3	1.4
28	1.1	1.1	1.2	0.9	0.9	1.0	1.1	1.3
29	0.6	0.7	0.8	1.0	1.1	1.2	1.1	1.1
30	0.7	0.9	0.8	0.9	1.0	1.1	0.9	0.8
<b>Mean</b>	<b>1.10</b>	<b>1.12</b>	<b>1.10</b>	<b>1.11</b>	<b>1.10</b>	<b>1.10</b>	<b>1.58</b>	<b>1.07</b>
<b>SD</b>	<b>0.34</b>	<b>0.34</b>	<b>0.31</b>	<b>0.28</b>	<b>0.30</b>	<b>0.30</b>	<b>2.74</b>	<b>0.25</b>
	<b>1<sup>st</sup> month</b>				<b>2<sup>nd</sup> months</b>			
<b>Min</b>	0.70				0.65			
<b>Max</b>	1.73				5.10			
<b>Mean</b>	1.11				1.21			
<b>SD</b>	0.30				0.78			
<b>Median</b>	1.01				1.03			
<b>Z1</b>	0.023							
<b>p1</b>	0.982							

Z<sub>1</sub>: Z for Wilcoxon signed ranks test

p<sub>1</sub>: p value for Wilcoxon signed ranks test for comparing between 1<sup>st</sup> and 2<sup>nd</sup> month

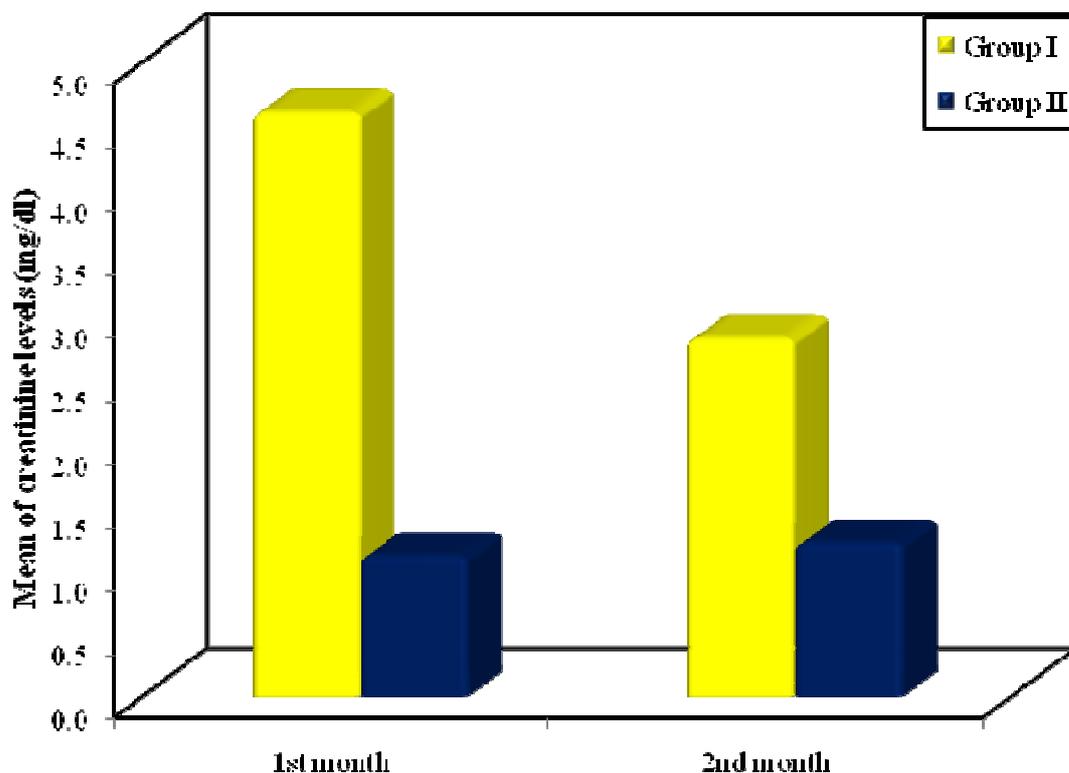
**Table (23): Comparison between the two studied groups in the 1st and 2nd month according to creatinine levels (mg/dl).**

Creatinine levels	Group I (n=30)	Group II (n=30)	Z	p
<b>1<sup>st</sup> month</b>				
Min. – Max.	0.60 – 104.25	0.70 – 1.73	0.237	0.813
Mean ± SD.	4.60 ± 18.83	1.11 ± 0.30		
Median	1.0	1.01		
<b>2<sup>nd</sup> month</b>				
Min. – Max.	0.68 – 51.45	0.65 – 5.10	0.340	0.734
Mean ± SD.	2.82 ± 9.20	1.21 ± 0.78		
Median	1.03	1.03		

Z: Z for Mann Whitney test

p: p value for Mann Whitney test for comparing between the two studied groups

\*: Statistically significant at  $p \leq 0.05$



**Figure (15): Comparison between the two studied groups in the 1<sup>st</sup> and 2<sup>nd</sup> month according to creatinine levels (mg/dl).**

**8. Comparison between the two studied groups according to Hemoglobin levels Hb (mg/dl)**

There was no statically significant difference between the patients in group I after one and two months of admission at all time of measurements (table 24) also in the group II after one and two months of admission at all time of measurements (table 25)  $p=0.371$  $p=0.829$  respectively.

There was no statically significant difference between the patients in group I and group II after one month and two months of admission at all time of measurements  $p=0.464$  $p=0.865$  respectively (table 26, figure 16).

**9. Comparison between the studied groups according to white blood cells count WBC ( $10^3$ /ul).**

There was statically significant difference between the patients in group I after one and two months of admission  $p=0.005$  (table 27) but there was no statistically significant difference in the group II after one and two months of admission at all time of measurements  $p=0.102$  (table 28).

Between group I and group II after one and two months of admission There was no statically significant difference  $p=0.824$   $p=0.243$  respectively (table 29, figure 17).

**Table (24): Comparison between the First four weeks and Second four weeks according to Hemoglobin levels Hb (mg/dl) in Group I.**

Cases	First four weeks				Second four weeks			
	Hb1	Hb2	Hb3	Hb4	Hb5	Hb6	Hb7	Hb8
1	10.0	9.5	10.0	12.0	11.0	11.0	11.5	11.8
2	9.0	8.0	10.2	11.0	11.2	11.3	11.0	11.3
3	13.0	12.5	1.3	13.0	13.0	12.9	13.0	12.6
4	12.9	13.0	12.6	12.3	11.9	12.1	12.2	12.5
5	14.0	13.9	14.2	13.9	14.0	13.7	13.9	13.3
6	11.5	11.6	11.5	11.4	11.0	11.1	10.2	10.8
7	8.0	8.2	9.8	9.9	10.1	10.0	10.5	10.2
8	12.3	12.4	12.2	12.5	12.7	12.5	12.3	12.4
9	14.0	13.5	13.8	13.2	13.5	13.3	13.5	13.2
10	9.0	9.6	9.7	8.0	8.7	9.2	9.4	9.3
11	11.5	11.3	11.3	12.0	11.8	11.5	12.2	12.0
12	12.3	11.0	11.2	11.0	11.3	11.5	11.6	11.7
13	11.2	11.8	11.9	11.5	11.7	11.8	11.9	11.3
14	13.0	13.5	13.2	13.3	12.9	12.8	12.9	13.0
15	14.0	14.2	13.9	13.8	13.9	13.8	14.0	13.6
16	12.3	12.4	12.0	12.2	12.5	12.0	12.2	12.5
17	8.5	9.5	10.2	9.8	10.3	10.0	10.5	10.0
18	11.5	11.3	11.0	11.5	11.8	11.2	11.0	11.5
19	8.5	10.0	9.8	9.6	9.8	10.0	10.2	10.1
20	10.2	10.8	11.0	10.5	10.8	10.9	10.2	10.4
21	11.5	12.0	11.3	11.9	11.0	11.1	11.2	11.4
22	11.2	11.3	11.4	10.9	10.1	10.2	10.2	10.8
23	15.0	14.0	13.5	14.0	13.9	14.2	14.6	14.3
24	12.2	12.9	12.3	11.9	11.9	11.8	12.0	12.1
25	10.0	9.2	8.3	10.1	10.2	9.6	10.2	9.2
26	8.6	8.9	10.2	10.1	10.2	9.8	9.6	9.9
27	13.2	13.3	12.8	12.6	13.4	12.9	13.0	13.1
28	11.2	11.5	11.3	11.9	12.2	11.5	10.6	11.9
29	14.2	13.3	13.2	12.9	12.8	12.9	12.5	12.6
30	14.0	13.2	13.8	13.3	13.6	13.7	13.6	13.5
<b>Mean</b>	<b>11.59</b>	<b>11.59</b>	<b>11.30</b>	<b>11.73</b>	<b>11.77</b>	<b>11.68</b>	<b>11.72</b>	<b>11.74</b>
<b>SD</b>	<b>1.98</b>	<b>1.80</b>	<b>2.41</b>	<b>1.45</b>	<b>1.41</b>	<b>1.38</b>	<b>1.42</b>	<b>1.34</b>
	<b>1<sup>st</sup> month</b>				<b>2<sup>nd</sup> month</b>			
<b>Min</b>	8.98				9.15			
<b>Max</b>	14.13				14.25			
<b>Mean</b>	11.55				11.73			
<b>SD</b>	1.64				1.37			
<b>Median</b>	11.51				11.61			
<b>Z1</b>	0.985							
<b>p1</b>	0.371							

Z<sub>1</sub>: Z for Wilcoxon signed ranks test

p<sub>1</sub>: p value for Wilcoxon signed ranks test for comparing between 1<sup>st</sup> and 2<sup>nd</sup> month

**Table (25): Comparison between the First four weeks and Second four weeks according to Hemoglobin levels Hb (mg/dl) in Group II.**

Cases	First four weeks				Second four weeks			
	Hb1	Hb2	Hb3	Hb4	Hb5	Hb6	Hb7	Hb8
1	13.0	12.8	12.5	12.0	12.2	12.1	12.5	12.3
2	9.8	2.2	10.0	10.2	11.0	10.8	9.8	9.2
3	12.2	12.3	11.9	12.4	12.2	12.9	12.9	12.8
4	13.2	13.2	12.9	12.8	13.2	13.1	12.8	12.9
5	8.3	9.2	10.1	9.7	9.5	7.2	10.0	10.2
6	13.0	13.2	12.9	12.8	13.1	13.0	12.5	12.6
7	14.2	14.3	13.7	13.6	13.7	13.8	13.4	13.0
8	13.6	13.7	13.9	14.0	13.8	13.8	13.9	13.7
9	9.8	9.4	2.2	10.0	9.8	9.7	9.6	9.7
10	13.2	13.4	12.0	12.6	12.7	12.3	12.5	12.4
11	10.5	10.6	10.6	10.8	10.2	10.1	10.2	10.6
12	14.2	14.3	14.1	13.8	13.9	14.0	14.1	13.8
13	13.2	10.2	11.1	98.0	10.2	10.1	11.0	11.2
14	13.2	13.4	12.9	12.8	13.1	12.2	12.8	12.9
15	13.2	13.2	12.9	12.8	12.7	13.1	13.2	13.0
16	12.2	13.0	13.2	12.0	13.0	13.0	13.0	13.0
17	8.2	9.3	9.4	10.1	10.2	9.8	9.4	9.8
18	9.8	9.6	9.9	10.1	9.5	10.2	10.3	10.4
19	12.2	12.6	12.5	11.0	11.2	11.5	11.6	11.7
20	14.2	14.1	13.9	13.8	14.1	14.2	14.3	13.9
21	7.4	10.1	10.2	9.4	9.6	10.2	9.8	10.2
22	12.8	12.6	11.2	11.5	12.4	12.6	12.7	12.3
23	7.4	10.0	10.2	9.8	9.7	10.2	10.8	10.9
24	12.6	12.7	12.7	11.9	11.6	11.7	11.9	12.0
25	16.0	14.0	13.9	13.7	13.6	13.7	13.8	13.7
26	12.6	12.7	12.5	12.3	12.0	12.1	12.2	12.3
27	10.1	9.8	9.7	10.2	9.3	9.4	9.5	9.8
28	13.2	13.3	12.9	12.0	12.2	12.4	12.4	12.6
29	8.2	8.4	10.0	9.6	9.5	9.2	9.8	10.0
30	13.0	12.8	12.5	12.0	12.2	12.1	12.5	12.3
<b>Mean</b>	<b>11.82</b>	<b>11.68</b>	<b>11.61</b>	<b>14.59</b>	<b>11.71</b>	<b>11.68</b>	<b>11.84</b>	<b>11.84</b>
<b>SD</b>	<b>2.28</b>	<b>2.54</b>	<b>2.31</b>	<b>15.82</b>	<b>1.60</b>	<b>1.74</b>	<b>1.55</b>	<b>1.42</b>
	<b>1<sup>st</sup> month</b>				<b>2<sup>nd</sup> month</b>			
<b>Min</b>	7.85				9.23			
<b>Max</b>	33.13				14.13			
<b>Mean</b>	12.43				11.77			
<b>SD</b>	4.36				1.54			
<b>Median</b>	12.55				12.28			
<b>Z1</b>					0.216			
<b>p1</b>					0.829			

Z<sub>1</sub>: Z for Wilcoxon signed ranks test

p<sub>1</sub>: p value for Wilcoxon signed ranks test for comparing between 1<sup>st</sup> and 2<sup>nd</sup> month

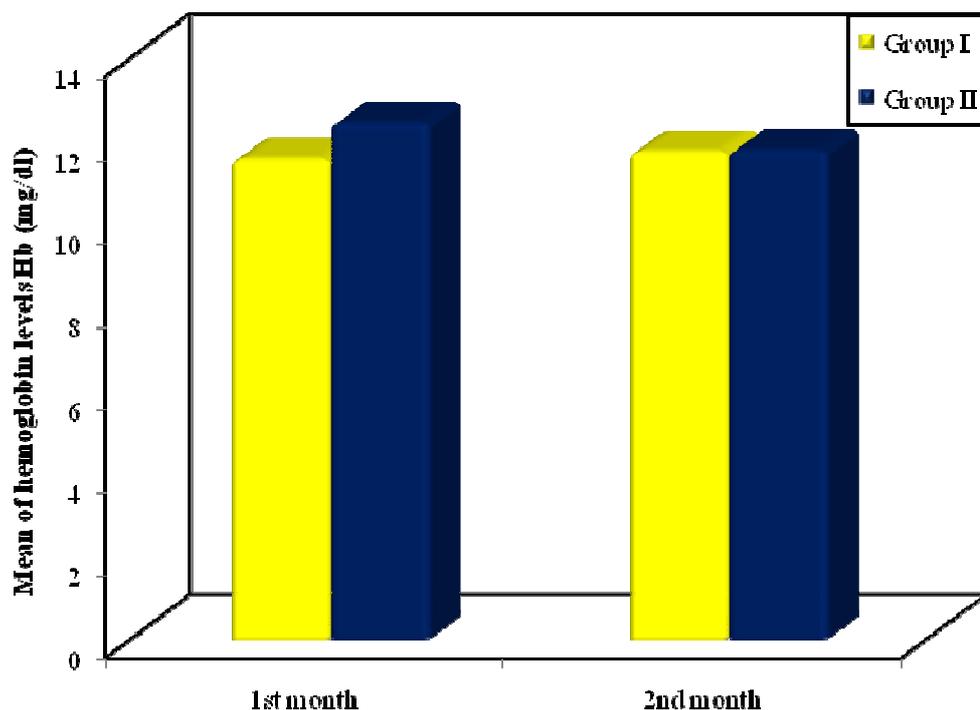
**Table (26):** Comparison between the two studied groups in the 1<sup>st</sup> and 2<sup>nd</sup> month according to Hemoglobin levels Hb (mg/dl).

Hemoglobin	Group I (n=30)	Group II (n=30)	Z	p
<b>1<sup>st</sup> month</b>				
Min. – Max.	8.98 – 14.13	7.85 – 33.13	0.732	0.464
Mean ± SD.	11.55 ± 1.64	12.43 ± 4.36		
Median	11.51	12.55		
<b>2<sup>nd</sup> month</b>				
Min. – Max.	9.15 – 14.25	9.23 – 14.13	0.170	0.865
Mean ± SD.	11.73 ± 1.37	11.77 ± 1.54		
Median	11.61	12.28		

Z: Z for Mann Whitney test

p: p value for Mann Whitney test for comparing between the two studied groups

\*: Statistically significant at  $p \leq 0.05$



**Figure (16):** Comparison between the two studied groups in the 1<sup>st</sup> and 2<sup>nd</sup> month according to Hemoglobin levels Hb (mg/dl).

**Table (27): Comparison between the First four weeks and Second four weeks according to white blood cells count WBC ( $10^3/ul$ ) in Group I.**

Cases	First four weeks				Second four weeks			
	WBC1	WBC2	WBC3	WBC4	WBC5	WBC6	WBC7	WBC8
1	16.0	15.0	11.0	11.0	9.0	9.5	7.5	7.8
2	20.0	21.0	17.0	16.7	14.0	11.0	9.0	9.0
3	7.0	7.0	9.5	7.2	11.0	11.0	12.0	11.7
4	11.2	11.0	11.3	11.4	11.2	13.2	13.0	12.0
5	14.0	13.0	9.0	7.0	7.5	7.6	7.6	8.0
6	15.0	16.0	10.0	11.0	11.7	12.0	13.2	14.5
7	4.2	4.3	5.6	7.0	7.2	6.2	7.0	7.1
8	9.0	9.2	8.0	8.4	9.2	9.0	7.0	7.2
9	12.0	12.5	12.9	11.0	11.0	10.0	10.5	10.7
10	16.0	14.8	18.2	16.1	15.0	12.9	12.5	10.2
11	12.0	12.6	11.0	9.0	9.2	7.0	7.5	7.6
12	11.0	12.5	16.0	14.0	12.0	12.0	12.8	12.5
13	8.0	8.3	8.2	9.0	9.0	9.2	10.0	11.0
14	9.2	7.1	8.0	8.7	7.0	6.5	6.7	7.0
15	20.0	14.0	13.3	12.6	12.5	8.0	8.6	8.3
16	13.0	13.8	13.2	12.0	11.0	11.5	10.0	10.0
17	14.0	14.6	14.0	12.0	16.0	13.0	13.2	13.0
18	9.0	9.5	8.0	8.0	8.5	8.2	8.5	8.0
19	13.0	13.2	13.3	12.0	12.8	12.5	11.0	11.2
20	8.5	8.8	8.2	8.9	9.0	11.0	11.2	11.2
21	10.6	12.0	11.7	15.0	14.7	14.2	14.3	13.0
22	9.0	11.0	10.5	12.0	8.0	8.5	8.2	8.0
23	7.5	7.9	7.9	8.0	8.5	8.3	8.9	11.0
24	16.0	16.5	15.0	16.2	15.6	15.3	12.0	12.2
25	28.0	16.0	12.0	9.2	7.1	7.4	8.0	7.6
26	16.0	14.2	14.1	12.3	11.0	11.7	10.3	10.1
27	27.0	20.0	14.0	13.8	12.6	12.3	11.2	10.3
28	12.3	13.0	16.0	14.2	14.1	13.2	12.6	11.2
29	12.6	14.3	14.9	10.2	10.3	8.7	9.3	9.1
30	12.0	12.6	11.0	10.3	8.7	8.5	8.6	8.3
<b>Mean</b>	<b>13.10</b>	<b>12.52</b>	<b>11.76</b>	<b>11.14</b>	<b>10.81</b>	<b>10.31</b>	<b>10.07</b>	<b>9.96</b>
<b>SD</b>	<b>5.35</b>	<b>3.71</b>	<b>3.16</b>	<b>2.81</b>	<b>2.67</b>	<b>2.45</b>	<b>2.23</b>	<b>2.07</b>
	<b>1<sup>st</sup> month</b>				<b>2<sup>nd</sup> month</b>			
<b>Min</b>	5.28				6.80			
<b>Max</b>	18.70				14.05			
<b>Mean</b>	12.13				10.29			
<b>SD</b>	3.30				2.19			
<b>Median</b>	12.60				10.58			
<b>Z1</b>	2.818*							
<b>p1</b>	0.005*							

Z<sub>1</sub>: Z for Wilcoxon signed ranks test

p<sub>1</sub>: p value for Wilcoxon signed ranks test for comparing between 1<sup>st</sup> and 2<sup>nd</sup> month

**Table (28): Comparison between the First four weeks and Second four weeks according to white blood cells count WBC ( $10^3/ul$ ) in Group II.**

Cases	First four weeks				Second four weeks			
	WBC1	WBC2	WBC3	WBC4	WBC5	WBC6	WBC7	WBC8
1	12.0	12.2	13.0	13.5	13.8	13.3	13.8	14.0
2	34.0	17.0	14.2	14.0	12.0	12.3	13.0	12.3
3	15.5	12.3	12.2	17.3	18.2	16.0	15.8	13.2
4	8.0	8.4	7.9	7.9	8.9	8.2	7.3	7.6
5	4.3	6.2	7.0	2.4	8.5	8.3	9.0	9.3
6	6.2	7.3	8.3	8.2	8.2	9.0	8.5	9.1
7	7.8	7.6	7.4	10.2	10.3	9.2	9.4	10.2
8	16.0	15.2	15.3	15.6	13.5	13.2	13.2	12.5
9	6.9	9.7	9.6	10.0	10.1	9.8	9.7	9.6
10	7.6	7.4	8.0	8.2	2.1	8.5	8.7	8.6
11	16.2	14.0	14.2	14.3	13.9	14.0	14.0	13.7
12	6.2	6.3	10.0	10.9	14.0	12.6	11.0	10.8
13	6.4	8.2	8.9	9.0	7.2	7.4	7.6	7.2
14	13.0	12.5	12.6	12.7	12.2	12.0	8.0	9.6
15	12.2	12.3	11.0	9.0	9.5	2.6	10.0	8.0
16	7.2	7.3	7.2	7.3	6.8	8.0	8.5	8.4
17	14.2	16.0	16.2	13.0	12.0	12.6	11.0	11.2
18	17.0	17.2	16.0	16.2	15.3	15.4	16.2	16.3
19	6.5	7.2	9.3	10.2	9.1	2.0	9.2	2.5
20	11.2	11.5	11.9	15.0	15.2	14.8	14.2	15.5
21	14.0	14.2	16.2	13.2	13.5	15.0	9.0	9.2
22	7.2	7.5	9.0	9.5	9.8	12.0	17.2	13.5
23	15.2	15.6	16.0	14.0	12.1	12.2	11.0	10.2
24	11.3	11.2	14.0	16.0	12.2	12.4	12.6	12.4
25	15.2	15.0	13.0	13.3	13.4	13.2	13.8	13.3
26	13.6	14.0	17.2	14.2	14.3	14.2	13.0	12.6
27	22.0	16.0	11.0	13.0	12.0	12.6	10.2	10.1
28	12.6	12.4	12.9	8.0	8.2	8.4	8.6	8.7
29	16.0	14.2	13.9	15.7	13.8	14.3	11.1	9.2
30	12.0	12.2	13.0	13.5	1.8	13.3	13.8	14.0
<b>Mean</b>	<b>12.25</b>	<b>11.60</b>	<b>11.88</b>	<b>11.84</b>	<b>11.06</b>	<b>11.23</b>	<b>11.28</b>	<b>10.76</b>
<b>SD</b>	<b>5.92</b>	<b>3.51</b>	<b>3.11</b>	<b>3.41</b>	<b>3.66</b>	<b>3.47</b>	<b>2.75</b>	<b>2.88</b>
	<b>1<sup>st</sup> month</b>				<b>2<sup>nd</sup> month</b>			
<b>Min</b>	4.98				5.70			
<b>Max</b>	19.80				15.80			
<b>Mean</b>	11.89				11.08			
<b>SD</b>	3.58				2.72			
<b>Median</b>	12.68				11.53			
<b>Z1</b>	1.635							
<b>p1</b>	0.102							

Z<sub>1</sub>: Z for Wilcoxon signed ranks test

p<sub>1</sub>: p value for Wilcoxon signed ranks test for comparing between 1<sup>st</sup> and 2<sup>nd</sup> month

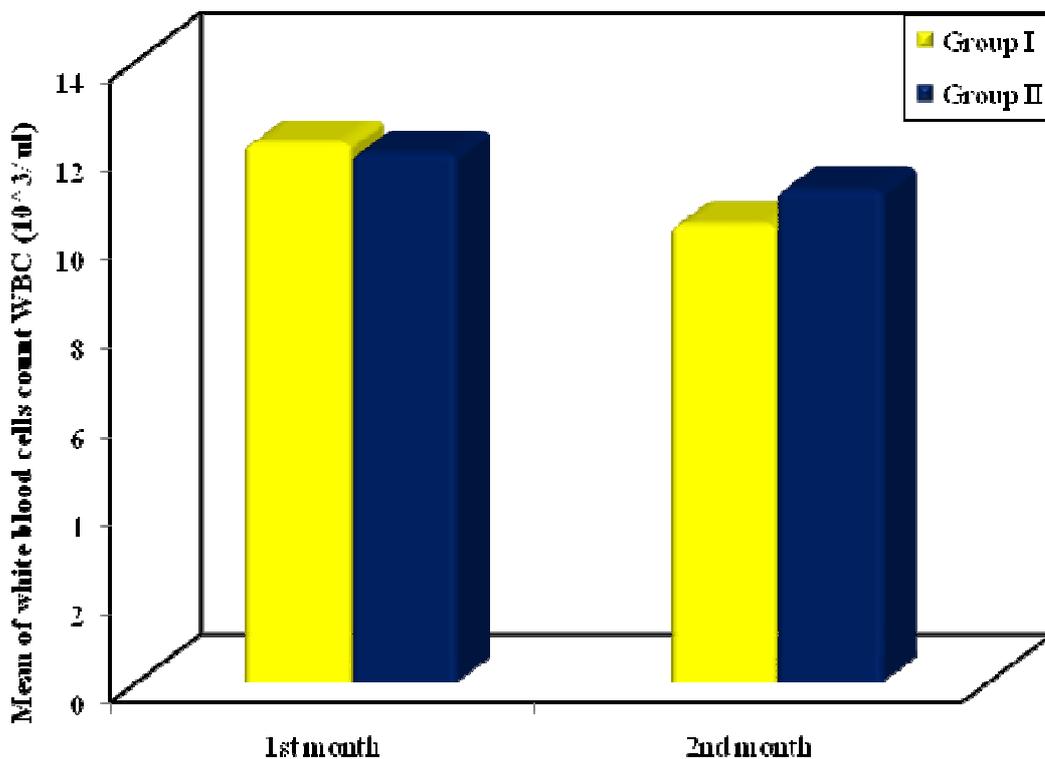
**Table (29): Comparison between the two studied groups in the 1st and 2nd month according to white blood cells count WBC ( $10^3/ul$ ).**

WBC	Group I (n=30)	Group II (n=30)	Z	p
<b>1<sup>st</sup> month</b>				
Min. – Max.	5.28 – 18.70	4.98 – 19.80	0.222	0.824
Mean ± SD.	12.13 ± 3.30	11.89 ± 3.58		
Median	12.60	12.68		
<b>2<sup>nd</sup> month</b>				
Min. – Max.	6.80 – 14.05	5.70 – 15.80	1.168	0.243
Mean ± SD.	10.29 ± 2.19	11.08 ± 2.72		
Median	10.58	11.53		

Z: Z for Mann Whitney test

p: p value for Mann Whitney test for comparing between the two studied groups

\*: Statistically significant at  $p \leq 0.05$



**Figure (17): Comparison between the two studied groups in the 1<sup>st</sup> and 2<sup>nd</sup> month according to white blood cells count WBC ( $10^3/ul$ ).**

7) Comparison between the studied groups according to platlate count  $10^3/\text{ul}$

There was no statically significant difference between the patients in group I after one and two months of admission at all time of measurements  $p=0.114$  (table 30)also there was no statistically significant difference in the group II after one and two months of admission at all time of measurements  $p=0.773$  (table 31).

Between group I and group II after one and two months of admission There was no statically significant difference  $p=0.749p=0.438$  respectively (table 32, figure 18).

**Table (30): Comparison between the First four weeks and Second four weeks according to platlate count  $10^3/\text{ul}$  in Group I.**

Cases	First four weeks				Second four weeks			
	Platlate1	Platlate2	Platlate3	Platlate4	Platlate5	Platlate6	Platlate7	Platlate8
1	236.0	240.0	332.0	270.0	310.0	269.0	280.0	302.0
2	214.0	221.0	222.0	232.0	213.0	219.0	221.0	225.0
3	410.0	408.0	409.0	399.0	398.0	400.0	414.0	412.0
4	177.0	170.0	167.0	178.0	176.0	177.0	170.0	176.0
5	216.0	217.0	216.0	220.0	214.0	216.0	214.0	215.0
6	310.0	314.0	313.0	330.0	312.0	316.0	315.0	317.0
7	18.0	200.0	199.0	198.0	200.0	201.0	210.0	208.0
8	390.0	392.0	400.0	380.0	393.0	398.0	400.0	395.0
9	229.0	220.0	235.0	223.0	222.0	230.0	225.0	216.0
10	316.0	316.0	324.0	322.0	321.0	320.0	313.0	315.0
11	306.0	333.0	312.0	315.0	309.0	331.0	320.0	323.0
12	170.0	169.0	177.0	170.0	176.0	178.0	177.0	180.0
13	415.0	420.0	409.0	415.0	416.0	430.0	422.0	426.0
14	312.0	314.0	300.0	315.0	316.0	317.0	316.0	315.0
15	214.0	222.0	230.0	220.0	225.0	226.0	220.0	223.0
16	370.0	375.0	366.0	372.0	376.0	373.0	360.0	365.0
17	276.0	280.0	277.0	279.0	283.0	280.0	277.0	282.0
18	310.0	315.0	305.0	307.0	309.0	308.0	300.0	310.0
19	115.0	117.0	107.0	120.0	113.0	113.0	124.0	120.0
20	216.0	221.0	218.0	217.0	219.0	221.0	220.0	220.0
21	270.0	266.0	277.0	270.0	266.0	270.0	273.0	765.0
22	316.0	320.0	311.0	315.0	316.0	300.0	310.0	326.0
23	216.0	230.0	220.0	225.0	216.0	230.0	235.0	229.0
24	216.0	209.0	232.0	214.0	230.0	216.0	216.0	213.0
25	292.0	293.0	294.0	296.0	282.0	294.0	296.0	298.0
26	216.0	222.0	230.0	214.0	244.0	234.0	226.0	270.0
27	235.0	246.0	243.0	255.0	265.0	245.0	247.0	243.0
28	314.0	320.0	319.0	316.0	315.0	290.0	280.0	305.0
29	242.0	251.0	244.0	250.0	266.0	236.0	241.0	239.0
30	330.0	325.0	325.0	316.0	317.0	317.0	315.0	320.0
Mean	262.23	271.53	273.77	271.77	273.93	271.83	271.23	291.77
SD	85.43	73.91	72.68	70.79	71.24	72.19	71.03	114.77
	1 <sup>st</sup> month				2 <sup>nd</sup> month			
Min	114.75				117.50			
Max	414.75				423.50			
Mean	269.83				277.19			
SD	74.13				74.58			
Median	270.13				285.38			
t <sub>1</sub>	1.630							
t <sub>1</sub>	0.114							

t<sub>1</sub>: Paired t-test

p<sub>1</sub>: p value for Paired t-test for comparing between 1<sup>st</sup> and 2<sup>nd</sup> month

**Table (31): Comparison between the First four weeks and Second four weeks according to platlate count  $10^3/\text{ul}$  in Group II.**

Cases	First four weeks				Second four weeks			
	Platlate 1	Platlate 2	Platlate 3	Platlate 4	Platlate 5	Platlate 6	Platlate 7	Platlate 8
1	198.0	200.0	201.0	202.0	199.0	215.0	213.0	212.0
2	216.0	222.0	240.0	230.0	243.0	216.0	217.0	220.0
3	216.0	213.0	214.0	210.0	211.0	213.0	215.0	216.0
4	294.0	297.0	297.0	299.0	296.0	297.0	295.0	280.0
5	176.0	179.0	182.0	192.0	183.0	182.0	188.0	186.0
6	296.0	310.0	315.0	315.0	310.0	305.0	308.0	306.0
7	210.0	209.0	203.0	205.0	215.0	213.0	232.0	214.0
8	216.0	215.0	210.0	200.0	180.0	216.0	200.0	216.0
9	180.0	177.0	176.0	165.0	170.0	166.0	190.0	180.0
10	310.0	315.0	315.0	300.0	320.0	310.0	315.0	320.0
11	223.0	234.0	250.0	266.0	240.0	244.0	216.0	262.0
12	320.0	310.0	315.0	309.0	314.0	312.0	314.0	315.0
13	310.0	320.0	333.0	314.0	312.0	316.0	317.0	316.0
14	332.0	330.0	310.0	320.0	314.0	316.0	316.0	319.0
15	316.0	310.0	330.0	318.0	313.0	342.0	341.0	320.0
16	410.0	415.0	412.0	414.0	415.0	402.0	409.0	408.0
17	249.0	240.0	244.0	250.0	247.0	243.0	244.0	246.0
18	198.0	199.0	200.0	210.0	220.0	190.0	195.0	186.0
19	260.0	250.0	255.0	256.0	210.0	222.0	205.0	218.0
20	250.0	254.0	256.0	229.0	235.0	230.0	235.0	246.0
21	304.0	321.0	324.0	295.0	296.0	301.0	302.0	305.0
22	320.0	310.0	360.0	310.0	315.0	325.0	328.0	310.0
23	290.0	295.0	310.0	298.0	320.0	295.0	296.0	302.0
24	216.0	214.0	224.0	235.0	220.0	216.0	219.0	223.0
25	416.0	413.0	402.0	390.0	360.0	402.0	394.0	386.0
26	314.0	312.0	302.0	316.0	322.0	324.0	329.0	308.0
27	190.0	199.0	194.0	196.0	210.0	211.0	216.0	208.0
28	231.0	230.0	216.0	215.0	218.0	219.0	302.0	216.0
29	226.0	223.0	224.0	216.0	227.0	243.0	233.0	232.0
30	198.0	200.0	201.0	202.0	199.0	215.0	213.0	212.0
<b>Mean</b>	<b>262.83</b>	<b>263.87</b>	<b>267.17</b>	<b>262.57</b>	<b>261.13</b>	<b>263.37</b>	<b>266.57</b>	<b>262.93</b>
<b>SD</b>	<b>64.07</b>	<b>64.19</b>	<b>65.52</b>	<b>61.55</b>	<b>61.40</b>	<b>62.74</b>	<b>62.33</b>	<b>59.88</b>
	<b>1<sup>st</sup> month</b>				<b>2<sup>nd</sup> month</b>			
<b>Min</b>	174.50				176.50			
<b>Max</b>	412.75				408.50			
<b>Mean</b>	264.11				263.50			
<b>SD</b>	63.37				60.72			
<b>Median</b>	246.50				239.63			
<b>t<sub>1</sub></b>	0.291							
<b>t<sub>1</sub></b>	0.773							

t<sub>1</sub>: Paired t-test

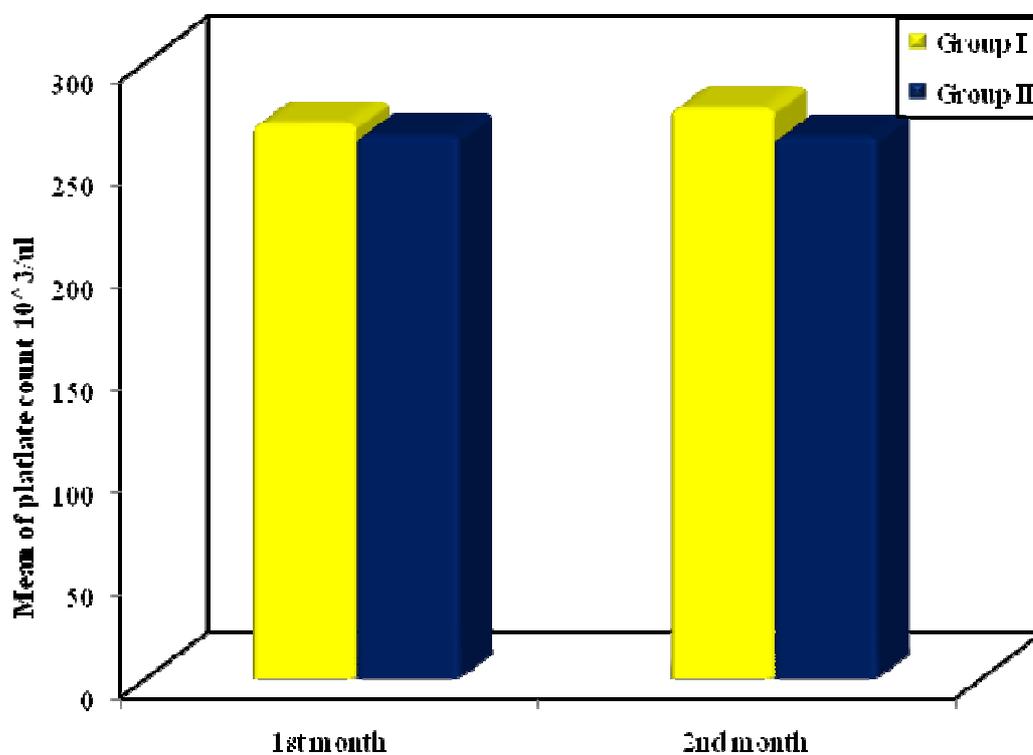
p<sub>1</sub>: p value for Paired t-test for comparing between 1<sup>st</sup> and 2<sup>nd</sup> month

**Table (32): Comparison between the two studied groups in the 1st and 2nd month according to platlate count  $10^3/\text{ul}$**

Platlate count	Group I (n=30)	Group II (n=30)	t	p
<b>1<sup>st</sup> month</b>				
Min. – Max.	114.75 – 414.75	174.50 – 412.75	0.321	0.749
Mean $\pm$ SD.	269.83 $\pm$ 74.13	264.11 $\pm$ 63.37		
Median	270.13	246.50		
<b>2<sup>nd</sup> month</b>				
Min. – Max.	117.50 – 423.50	176.50 – 408.50	0.780	0.438
Mean $\pm$ SD.	277.19 $\pm$ 74.58	263.50 $\pm$ 60.72		
Median	285.38	239.63		

t: Student t-test

p: p value for Student t-test for comparing between the two studied groups



**Figure (18): Comparison between the two studied groups in the 1<sup>st</sup> and 2<sup>nd</sup> month according to platlate count  $10^3/\text{ul}$ .**

#### **IV Assessment of Neurological Recovery**

##### **1. The Disability Rating Scale (DRS)**

In group I, there was an improvement in the DRS scores of 8.4 points from  $19.30 \pm \text{SD } 4.00$  to  $10.80 \pm \text{SD } 4.54$  while on the active drug in comparison to only 2 points from  $9.50 \pm \text{SD } 3.85$  to  $7.50 \pm \text{SD } 3.71$  in the second 4-week period when on placebo, There was statically significant difference between 1st and 2nd month  $p < 0.001$  (table 33, figure 19).

In group II, there was an improvement in the DRS of 6.83 points from  $23.10 \pm \text{SD } 2.29$  to  $16.27 \pm \text{SD } 2.55$  spontaneously during the first 4 weeks, but they recovered an additional 8.23 points from  $13.50 \pm \text{SD } 2.83$  to  $5.27 \pm \text{SD } 2.39$  during the 2nd 4 weeks on the active drug. There was statically significant difference between 1st and 2nd month  $p < 0.001$  (table 34, figure 20).

When comparing the amount of change between the groups, there was statistical difference in the recovery within the first 4 weeks between group I (on active drug) versus group II (placebo)  $p < 0.001$  but no statistically significant amount of change during the second 4-week between group I (placebo) and group II (on active drug) ( $P = 0.228$ ) (table 35, figure 21).

**Table (33): Comparison between the First four weeks and Second four weeks according to The Disability Rating Scale (DRS) in Group I.**

Cases	First four weeks				Second four weeks			
	DRS1	DRS2	DRS3	DRS4	DRS5	DRS6	DRS7	DRS8
1	19.0	17.0	10.0	6.0	6.0	6.0	4.0	3.0
2	20.0	17.0	11.0	19.0	10.0	8.0	8.0	8.0
3	16.0	11.0	10.0	6.0	6.0	5.0	5.0	4.0
4	20.0	17.0	15.0	13.0	12.0	12.0	12.0	12.0
5	20.0	17.0	15.0	12.0	11.0	10.0	10.0	9.0
6	21.0	20.0	17.0	15.0	15.0	15.0	15.0	14.0
7	21.0	20.0	16.0	15.0	13.0	13.0	13.0	11.0
8	17.0	12.0	11.0	7.0	6.0	5.0	5.0	4.0
9	16.0	14.0	12.0	8.0	7.0	7.0	6.0	6.0
10	19.0	17.0	10.0	6.0	6.0	6.0	4.0	3.0
11	11.0	7.0	4.0	3.0	3.0	3.0	2.0	2.0
12	14.0	12.0	11.0	7.0	7.0	7.0	6.0	6.0
13	13.0	10.0	9.0	9.0	8.0	6.0	6.0	6.0
14	21.0	19.0	17.0	15.0	14.0	13.0	12.0	11.0
15	24.0	22.0	20.0	19.0	18.0	17.0	17.0	16.0
16	16.0	12.0	7.0	5.0	4.0	4.0	4.0	3.0
17	15.0	12.0	7.0	6.0	6.0	6.0	5.0	5.0
18	11.0	9.0	8.0	7.0	6.0	6.0	6.0	5.0
19	23.0	21.0	20.0	15.0	12.0	12.0	11.0	11.0
20	23.0	21.0	20.0	16.0	14.0	14.0	13.0	12.0
21	23.0	17.0	15.0	10.0	8.0	8.0	7.0	6.0
22	19.0	16.0	10.0	6.0	5.0	4.0	4.0	3.0
23	20.0	17.0	10.0	7.0	6.0	6.0	6.0	5.0
24	26.0	23.0	17.0	16.0	15.0	13.0	12.0	11.0
25	16.0	14.0	13.0	10.0	9.0	8.0	7.0	6.0
26	24.0	20.0	18.0	13.0	12.0	11.0	10.0	8.0
27	22.0	17.0	12.0	10.0	9.0	8.0	7.0	6.0
28	22.0	16.0	14.0	12.0	11.0	10.0	9.0	7.0
29	24.0	21.0	18.0	16.0	13.0	12.0	12.0	11.0
30	23.0	20.0	17.0	15.0	13.0	12.0	12.0	11.0
<b>Mean</b>	<b>19.30</b>	<b>16.27</b>	<b>13.13</b>	<b>10.80</b>	<b>9.50</b>	<b>8.90</b>	<b>8.33</b>	<b>7.50</b>
<b>SD</b>	<b>4.00</b>	<b>4.16</b>	<b>4.30</b>	<b>4.54</b>	<b>3.85</b>	<b>3.71</b>	<b>3.83</b>	<b>3.71</b>
	<b>1<sup>st</sup> month</b>				<b>2<sup>nd</sup> month</b>			
<b>Min</b>	6.25				2.50			
<b>Max</b>	21.25				17.00			
<b>Mean</b>	14.88				8.56			
<b>SD</b>	3.99				3.74			
<b>Median</b>	15.63				7.50			
<b>Z1</b>	4.787*							
<b>p1</b>	<0.001*							

Z<sub>1</sub>: Z for Wilcoxon signed ranks test

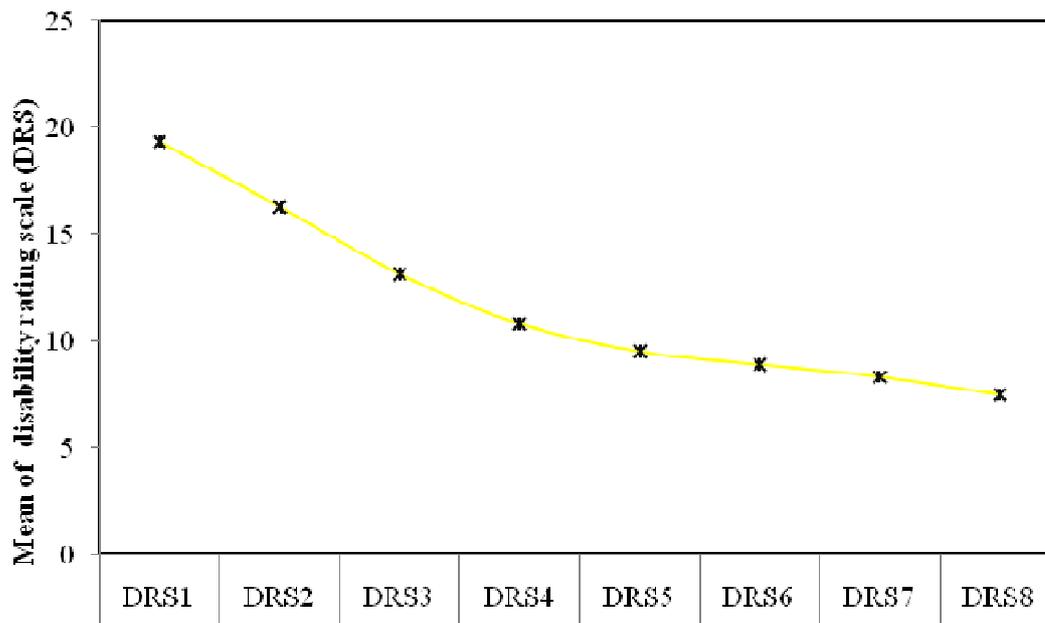
p<sub>1</sub>: p value for Wilcoxon signed ranks test for comparing between 1<sup>st</sup> and 2<sup>nd</sup> month

**Table (34): Comparison between the First four weeks and Second four weeks according to The Disability Rating Scale (DRS) in Group II.**

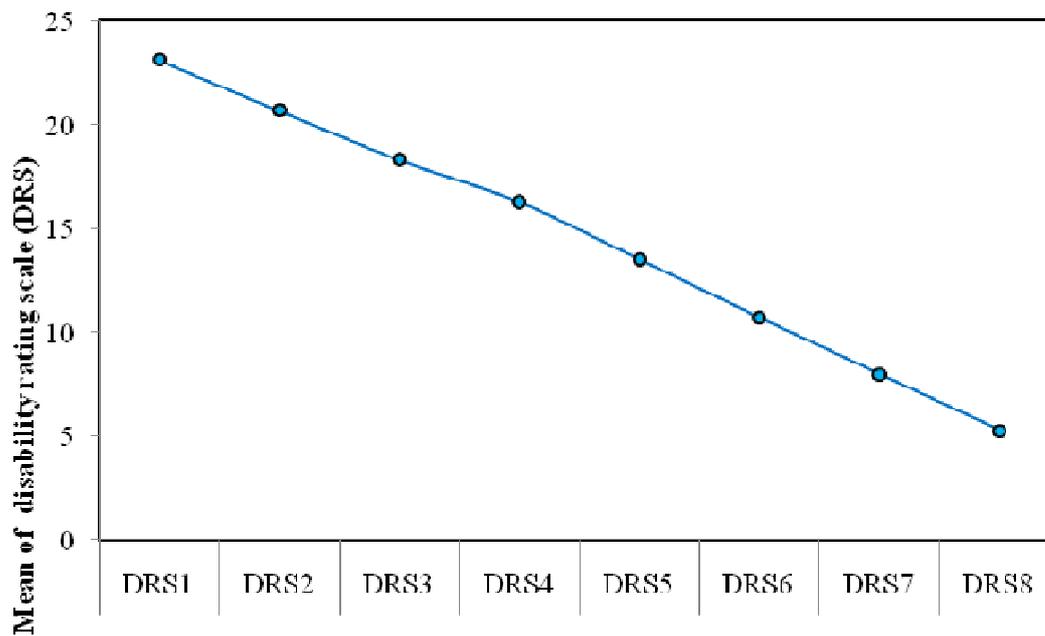
Cases	First four weeks				Second four weeks			
	DRS1	DRS2	DRS3	DRS4	DRS5	DRS6	DRS7	DRS8
1	23.0	21.0	19.0	17.0	12.0	10.0	7.0	5.0
2	24.0	19.0	17.0	15.0	12.0	10.0	7.0	3.0
3	25.0	22.0	16.0	14.0	12.0	9.0	7.0	6.0
4	21.0	18.0	16.0	14.0	11.0	9.0	7.0	5.0
5	26.0	24.0	20.0	19.0	17.0	15.0	12.0	10.0
6	23.0	20.0	16.0	13.0	13.0	11.0	7.0	4.0
7	20.0	18.0	17.0	15.0	12.0	10.0	6.0	6.0
8	16.0	13.0	12.0	10.0	7.0	4.0	3.0	2.0
9	24.0	20.0	19.0	17.0	15.0	12.0	9.0	6.0
10	19.0	17.0	14.0	11.0	8.0	5.0	2.0	1.0
11	27.0	25.0	22.0	19.0	18.0	15.0	12.0	9.0
12	22.0	18.0	17.0	16.0	13.0	12.0	9.0	5.0
13	20.0	16.0	15.0	14.0	11.0	8.0	7.0	5.0
14	23.0	20.0	16.0	14.0	8.0	4.0	3.0	1.0
15	23.0	22.0	20.0	17.0	16.0	12.0	10.0	6.0
16	25.0	23.0	20.0	17.0	14.0	11.0	8.0	4.0
17	23.0	22.0	17.0	15.0	14.0	12.0	10.0	6.0
18	26.0	24.0	23.0	21.0	18.0	16.0	12.0	9.0
19	24.0	21.0	20.0	17.0	15.0	12.0	9.0	5.0
20	24.0	21.0	18.0	17.0	14.0	11.0	6.0	4.0
21	23.0	20.0	19.0	17.0	15.0	11.0	8.0	6.0
22	25.0	22.0	21.0	18.0	15.0	12.0	10.0	6.0
23	23.0	21.0	17.0	16.0	13.0	10.0	7.0	4.0
24	22.0	21.0	17.0	15.0	12.0	8.0	6.0	2.0
25	25.0	23.0	22.0	20.0	17.0	14.0	13.0	10.0
26	24.0	23.0	20.0	18.0	15.0	11.0	8.0	5.0
27	24.0	22.0	20.0	19.0	17.0	14.0	12.0	9.0
28	21.0	19.0	18.0	16.0	13.0	10.0	6.0	3.0
29	25.0	24.0	22.0	20.0	16.0	13.0	9.0	6.0
30	23.0	21.0	19.0	17.0	12.0	10.0	7.0	5.0
<b>Mean</b>	<b>23.10</b>	<b>20.67</b>	<b>18.30</b>	<b>16.27</b>	<b>13.50</b>	<b>10.70</b>	<b>7.97</b>	<b>5.27</b>
<b>SD</b>	<b>2.29</b>	<b>2.63</b>	<b>2.56</b>	<b>2.55</b>	<b>2.83</b>	<b>2.93</b>	<b>2.72</b>	<b>2.39</b>
	<b>1<sup>st</sup> month</b>				<b>2<sup>nd</sup> month</b>			
<i>Min</i>	12.75				4.0			
<i>Max</i>	23.50				13.75			
<i>Mean</i>	19.58				9.36			
<i>SD</i>	2.38				2.62			
<i>Median</i>	19.88				9.00			
<i>Z1</i>	4.786*							
<i>p1</i>	<0.001*							

Z<sub>1</sub>: Z for Wilcoxon signed ranks test

p<sub>1</sub>: p value for Wilcoxon signed ranks test for comparing between 1<sup>st</sup> and 2<sup>nd</sup> month



**Figure (19):** Distribution of studied cases according to The Disability Rating Scale (DRS) in Group I (Amantadine first 4 weeks, placebo second 4 weeks).



**Figure (20):** Distribution of studied cases according to The Disability Rating Scale (DRS) in Group II (placebo first 4 weeks, Amantadine second 4 weeks).

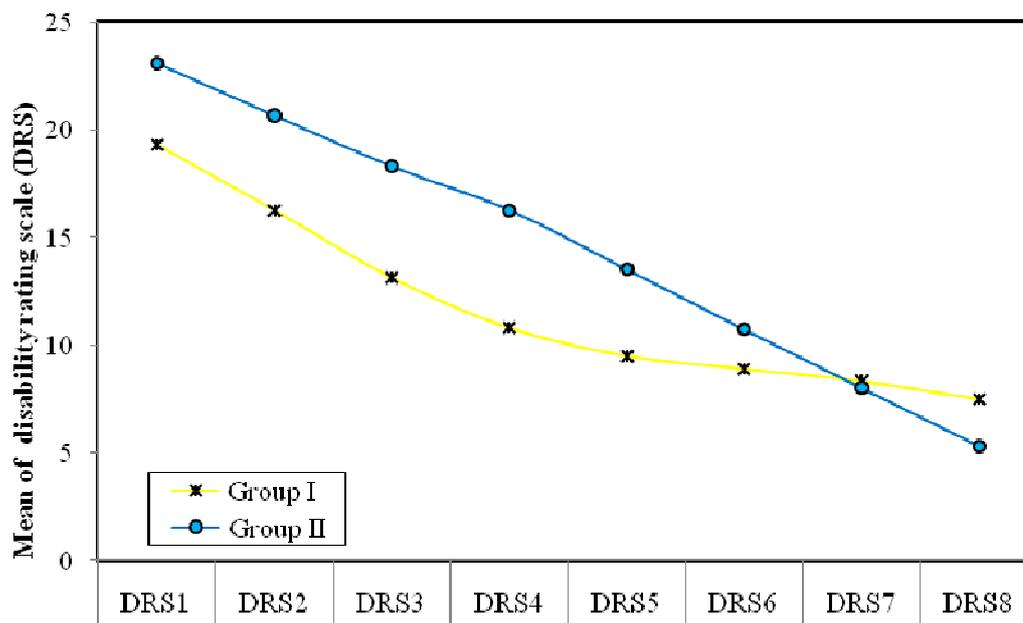
**Table (35): Comparison between the two studied groups in the 1st and 2nd month according to The Disability Rating Scale (DRS).**

DRS	Group I (n=30)	Group II (n=30)	Z	p
<b>1<sup>st</sup> month</b>				
Min. – Max.	6.25 – 21.25	12.75 – 23.50	4.521*	<0.001*
Mean ± SD.	14.88 ± 3.99	19.58 ± 2.38		
Median	15.63	19.88		
<b>2<sup>nd</sup> month</b>				
Min. – Max.	2.50 – 17.0	4.0 – 13.75	1.206	0.228
Mean ± SD.	8.56 ± 3.74	9.36 ± 2.62		
Median	7.50	9.0		

Z: Z for Mann Whitney test

p: p value for Mann Whitney test for comparing between the two studied groups

\*: Statistically significant at  $p \leq 0.05$



**Figure (21): Comparison between the two studied groups according to The Disability Rating Scale (DRS).**

## **2. The Mini-mental Status Test (MMST)**

There was an improvement in the MMST scores of 9.96 points from  $12.07 \pm \text{SD } 6.18$  to  $22.03 \pm \text{SD } 3.42$  in group I on the active drug during the first 4 weeks of treatment in comparison to only 1.7 points from  $22.80 \pm \text{SD } 3.17$  to  $24.50 \pm \text{SD } 2.96$  points in the second 4-week period when they were on the placebo, There was statically significant difference between 1st and 2nd month  $p < 0.001$  (table 36, figure 22).

In group II (active drug second 4 weeks), there was an improvement in the MMST of 7 points from  $9.07 \pm \text{SD } 2.35$  to  $16.07 \pm \text{SD } 3.26$  spontaneously in the first 4 weeks, but the group gained a significant additional 7.23 points of recovery from  $19.57 \pm \text{SD } 2.98$  to  $26.80 \pm \text{SD } 1.71$  while on the active drug between the 5th week and the 8th week, There was statically significant difference between 1st and 2nd month  $p < 0.001$  (table 37, figure 23).

When comparing the amount of change between the groups, there was statistical difference in the recovery within the first 4 weeks between group I (on active drug) versus group II (placebo)  $p < 0.001$  but no statistically significant amount of change during the second 4-week between group I (placebo) and group II (on active drug) ( $P = 0.416$ ) (table 38, figure 24).

**Table (36): Comparison between the First four weeks and Second four weeks according to The Mini-mental Status Test (MMST) in Group I.**

Cases	First four weeks				Second four weeks			
	MMST1	MMST2	MMST3	MMST4	MMST5	MMST6	MMST7	MMST8
1	9.0	8.0	20.0	22.0	22.0	22.0	23.0	23.0
2	8.0	9.0	15.0	18.0	20.0	21.0	21.0	22.0
3	15.0	20.0	19.0	22.0	22.0	24.0	24.0	25.0
4	8.0	19.0	20.0	24.0	24.0	25.0	26.0	26.0
5	9.0	11.0	20.0	22.0	24.0	24.0	23.0	24.0
6	6.0	9.0	15.0	22.0	24.0	25.0	25.0	27.0
7	6.0	9.0	9.0	11.0	11.0	12.0	12.0	13.0
8	20.0	21.0	23.0	24.0	25.0	25.0	26.0	25.0
9	22.0	23.0	26.0	26.0	27.0	27.0	27.0	28.0
10	9.0	8.0	20.0	22.0	22.0	22.0	23.0	23.0
11	20.0	21.0	24.0	28.0	28.0	28.0	29.0	29.0
12	20.0	23.0	24.0	26.0	26.0	26.0	28.0	28.0
13	20.0	23.0	23.0	27.0	27.0	27.0	27.0	27.0
14	20.0	21.0	26.0	26.0	27.0	27.0	27.0	28.0
15	8.0	9.0	11.0	15.0	20.0	20.0	20.0	21.0
16	9.0	15.0	20.0	23.0	23.0	24.0	24.0	25.0
17	10.0	15.0	20.0	24.0	24.0	24.0	25.0	26.0
18	15.0	18.0	21.0	22.0	23.0	23.0	24.0	25.0
19	8.0	9.0	15.0	20.0	20.0	21.0	21.0	22.0
20	5.0	8.0	14.0	20.0	22.0	22.0	23.0	24.0
21	9.0	15.0	17.0	20.0	21.0	22.0	23.0	24.0
22	9.0	15.0	26.0	21.0	21.0	23.0	23.0	24.0
23	7.0	14.0	18.0	21.0	21.0	21.0	22.0	22.0
24	5.0	9.0	15.0	19.0	20.0	21.0	22.0	23.0
25	20.0	15.0	23.0	24.0	25.0	25.0	25.0	26.0
26	9.0	15.0	19.0	22.0	23.0	24.0	24.0	25.0
27	28.0	20.0	21.0	24.0	24.0	24.0	25.0	26.0
28	9.0	10.0	19.0	22.0	22.0	23.0	24.0	24.0
29	9.0	16.0	20.0	22.0	23.0	23.0	23.0	24.0
30	10.0	16.0	21.0	22.0	23.0	23.0	24.0	26.0
<b>Mean</b>	<b>12.07</b>	<b>14.80</b>	<b>19.47</b>	<b>22.03</b>	<b>22.80</b>	<b>23.27</b>	<b>23.77</b>	<b>24.50</b>
<b>SD</b>	<b>6.18</b>	<b>5.19</b>	<b>4.22</b>	<b>3.42</b>	<b>3.17</b>	<b>2.95</b>	<b>3.06</b>	<b>2.96</b>
	<b>1<sup>st</sup> month</b>				<b>2<sup>nd</sup> month</b>			
<i>Min</i>	8.75				12.00			
<i>Max</i>	24.25				28.50			
<i>Mean</i>	17.09				23.58			
<i>SD</i>	4.28				3.00			
<i>Median</i>	16.75				23.75			
<i>Z<sub>1</sub></i>	4.784*							
<i>p<sub>1</sub></i>	<0.001*							

Z<sub>1</sub>: Z for Wilcoxon signed ranks test

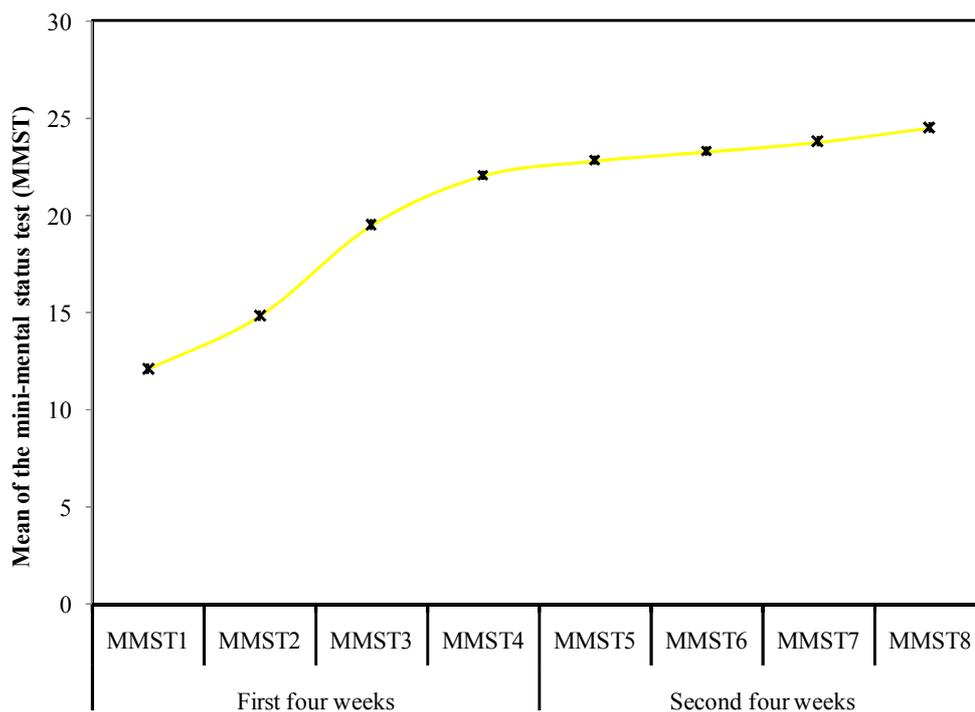
p<sub>1</sub>: p value for Wilcoxon signed ranks test for comparing between 1<sup>st</sup> and 2<sup>nd</sup> month

**Table (37): Comparison between the First four weeks and Second four weeks according to The Mini-mental Status Test (MMST) in Group II**

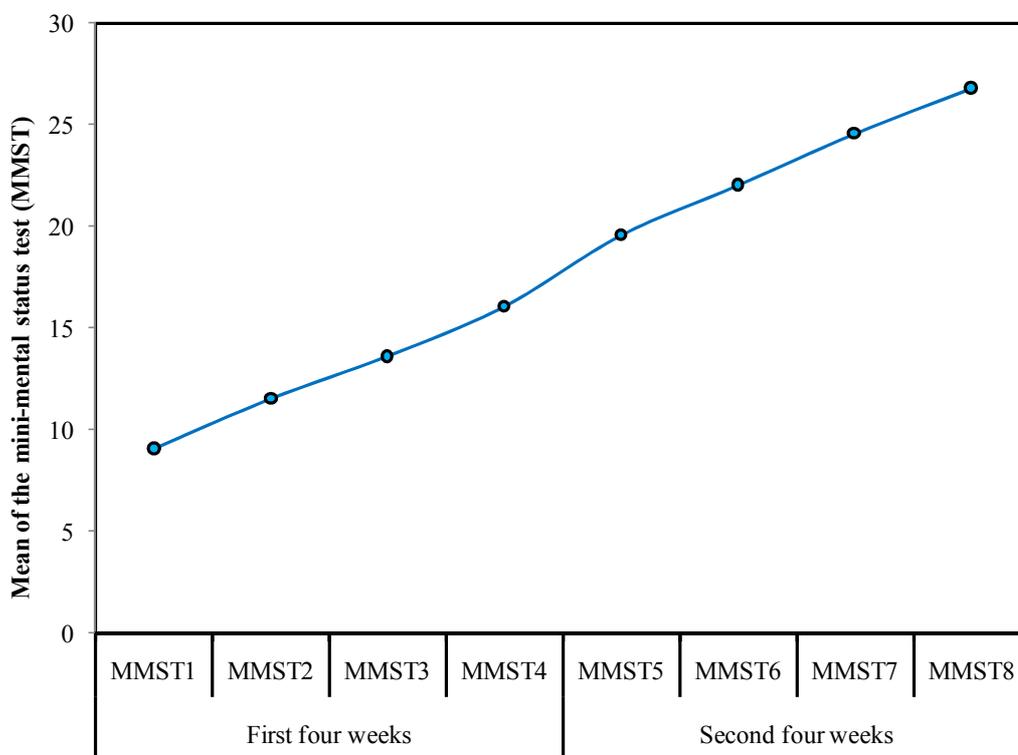
Cases	First four weeks				Second four weeks			
	MMST1	MMST2	MMST3	MMST4	MMST5	MMST6	MMST7	MMST8
1	8.0	12.0	14.0	15.0	19.0	22.0	24.0	25.0
2	10.0	15.0	16.0	28.0	23.0	25.0	26.0	29.0
3	7.0	10.0	13.0	15.0	29.0	21.0	24.0	26.0
4	11.0	12.0	14.0	19.0	22.0	25.0	28.0	30.0
5	9.0	12.0	15.0	16.0	21.0	23.0	24.0	26.0
6	7.0	9.0	13.0	16.0	21.0	24.0	26.0	27.0
7	8.0	10.0	13.0	16.0	19.0	23.0	25.0	27.0
8	14.0	17.0	19.0	20.0	22.0	25.0	27.0	29.0
9	8.0	11.0	12.0	16.0	19.0	22.0	24.0	26.0
10	16.0	18.0	20.0	21.0	22.0	25.0	28.0	29.0
11	8.0	9.0	11.0	14.0	17.0	20.0	23.0	25.0
12	9.0	11.0	12.0	15.0	18.0	21.0	23.0	26.0
13	10.0	13.0	14.0	16.0	19.0	21.0	22.0	26.0
14	9.0	13.0	14.0	16.0	19.0	22.0	26.0	29.0
15	10.0	13.0	17.0	19.0	22.0	24.0	28.0	29.0
16	9.0	14.0	16.0	17.0	23.0	26.0	27.0	28.0
17	8.0	8.0	9.0	11.0	15.0	18.0	21.0	24.0
18	5.0	8.0	12.0	15.0	19.0	21.0	24.0	25.0
19	8.0	10.0	11.0	13.0	15.0	19.0	22.0	26.0
20	9.0	12.0	15.0	16.0	20.0	23.0	25.0	27.0
21	11.0	14.0	16.0	17.0	20.0	23.0	25.0	27.0
22	9.0	11.0	14.0	15.0	20.0	22.0	24.0	27.0
23	10.0	12.0	15.0	16.0	20.0	23.0	26.0	28.0
24	11.0	13.0	15.0	17.0	20.0	23.0	26.0	28.0
25	5.0	8.0	9.0	12.0	15.0	18.0	21.0	24.0
26	10.0	11.0	13.0	14.0	17.0	18.0	22.0	25.0
27	6.0	8.0	10.0	11.0	15.0	19.0	22.0	24.0
28	12.0	14.0	16.0	18.0	21.0	24.0	26.0	29.0
29	7.0	8.0	10.0	13.0	16.0	19.0	24.0	26.0
30	8.0	10.0	11.0	15.0	19.0	22.0	24.0	27.0
<b>Mean</b>	<b>9.07</b>	<b>11.53</b>	<b>13.63</b>	<b>16.07</b>	<b>19.57</b>	<b>22.03</b>	<b>24.57</b>	<b>26.80</b>
<b>SD</b>	<b>2.35</b>	<b>2.61</b>	<b>2.70</b>	<b>3.26</b>	<b>2.98</b>	<b>2.30</b>	<b>2.03</b>	<b>1.71</b>
	<b>1<sup>st</sup> month</b>				<b>2<sup>nd</sup> month</b>			
<i>Min</i>	8.50				19.50			
<i>Max</i>	18.75				26.25			
<i>Mean</i>	12.58				23.24			
<i>SD</i>	2.51				2.04			
<i>Median</i>	12.25				23.50			
<i>Z1</i>	4.788*							
<i>p1</i>	<0.001*							

Z<sub>1</sub>: Z for Wilcoxon signed ranks test

p<sub>1</sub>: p value for Wilcoxon signed ranks test for comparing between 1<sup>st</sup> and 2<sup>nd</sup> month



**Figure (22):** Distribution of studied cases according to The Mini-mental Status Test (MMST) in Group I (Amantadine first 4 weeks, placebo second 4 weeks)



**Figure (23):** Distribution of studied cases according to The Mini-mental Status Test (MMST) in Group II (placebo first 4 weeks, Amantadine second 4 weeks).

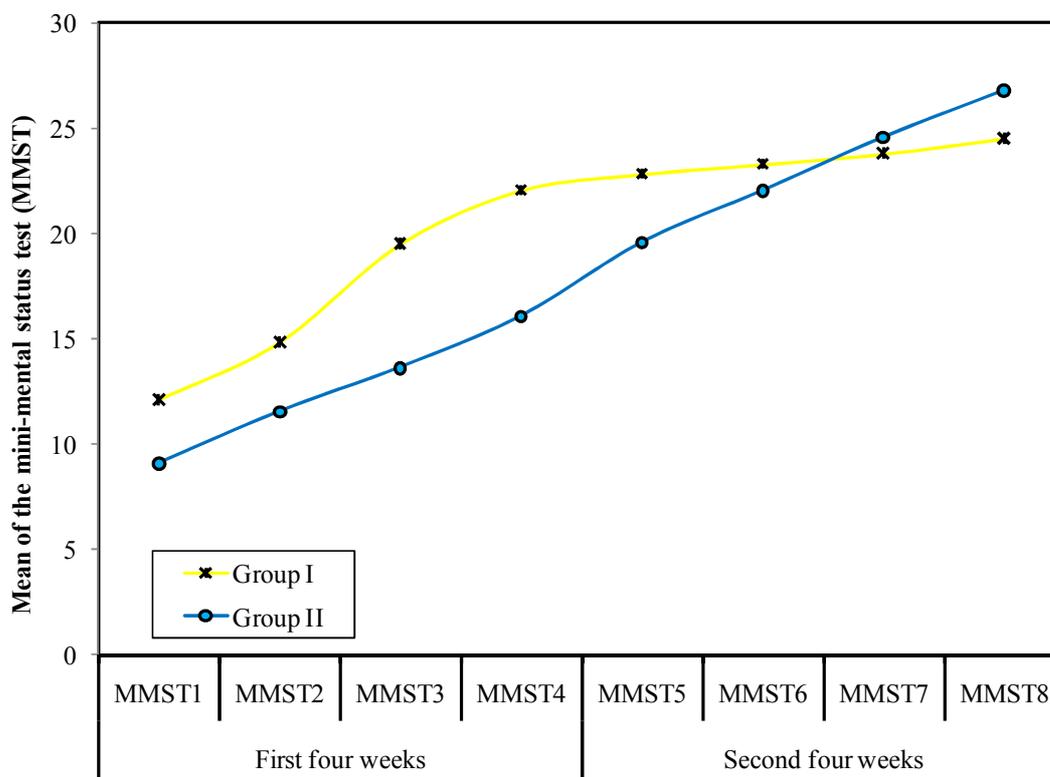
**Table (38): Comparison between the two studied groups in the 1st and 2nd month according to The Mini-mental Status Test (MMST)**

MMST	Group I (n=30)	Group II (n=30)	Z	p
<b>1<sup>st</sup> month</b>				
Min. – Max.	8.75 – 24.25	8.50 – 18.75	4.240*	<0.001*
Mean ± SD.	17.05 ± 4.28	12.58 ± 2.51		
Median	16.75	12.25		
<b>2<sup>nd</sup> month</b>				
Min. – Max.	12.0 – 28.50	19.50 – 26.25	0.814	0.416
Mean ± SD.	23.58 ± 3.0	23.24 ± 2.04		
Median	23.75	23.50		

Z: Z for Mann Whitney test

p: p value for Mann Whitney test for comparing between the two studied groups

\*: Statistically significant at  $p \leq 0.05$



**Figure (24): Comparison between the two studied groups according to The Mini-mental Status Test (MMST).**

### **3. The Glasgow Outcome Scale (GOS)**

There was an improvement in the GOS scores of 1.34 points from  $2.73 \pm \text{SD } 0.58$  to  $4.07 \pm \text{SD } 0.45$  in group I on the active drug during the first 4 weeks of treatment versus only 0.3 points from  $3.97 \pm \text{SD } 0.49$  to  $4.27 \pm \text{SD } 0.58$  in the second 4-week period when they were on the placebo, There was statically significant difference between 1st and 2nd month  $p1 < 0.001$  (table 39, figure 25).

In group II (active drug second 4 weeks), there was an improvement in the GOS of 0.37 points from  $2.73 \pm \text{SD } 0.58$  to  $3.27 \pm \text{SD } 0.45$  spontaneously in the first 4 weeks, but the group gained additional 0.93 points of recovery from  $3.67 \pm \text{SD } 0.48$  to  $4.60 \pm \text{SD } 0.50$  while on the active drug between the 5th week and the 8th week, There was statically significant difference between 1st and 2nd month  $p1 < 0.001$  (table 40, figure 26).

When comparing the amount of change between the groups, there was statistical difference in the recovery within the first 4 weeks between group I (on active drug) versus group II (placebo)  $p < 0.001$  but no statistically significant amount of change during the second 4-week between group I (placebo) and group II (on active drug) ( $P = 0.416$ ) (table 41, figure 27).

**Table (39): Comparison between the First four weeks and Second four weeks according to The Glasgow Outcome Scale (GOS) in Group I.**

Cases	First four weeks				Second four weeks			
	GOS1	GOS2	GOS3	GOS4	GOS5	GOS6	GOS7	GOS8
1	3.0	4.0	4.0	4.0	3.0	4.0	4.0	4.0
2	3.0	3.0	4.0	4.0	3.0	4.0	4.0	4.0
3	3.0	4.0	4.0	5.0	4.0	4.0	5.0	5.0
4	3.0	4.0	4.0	4.0	4.0	4.0	5.0	5.0
5	3.0	4.0	4.0	4.0	4.0	4.0	4.0	5.0
6	3.0	3.0	4.0	4.0	4.0	4.0	4.0	4.0
7	3.0	3.0	3.0	4.0	4.0	4.0	4.0	4.0
8	3.0	3.0	4.0	4.0	4.0	4.0	4.0	5.0
9	4.0	4.0	4.0	4.0	4.0	4.0	4.0	4.0
10	3.0	3.0	4.0	4.0	4.0	4.0	4.0	4.0
11	4.0	4.0	5.0	5.0	5.0	5.0	5.0	5.0
12	3.0	4.0	4.0	5.0	5.0	5.0	5.0	5.0
13	3.0	4.0	4.0	4.0	4.0	4.0	4.0	4.0
14	3.0	3.0	4.0	4.0	4.0	4.0	4.0	4.0
15	3.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0
16	3.0	4.0	4.0	5.0	5.0	5.0	5.0	5.0
17	3.0	4.0	4.0	4.0	4.0	4.0	4.0	4.0
18	3.0	4.0	4.0	4.0	4.0	4.0	4.0	5.0
19	3.0	3.0	3.0	4.0	4.0	4.0	4.0	4.0
20	2.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0
21	2.0	3.0	4.0	4.0	4.0	4.0	4.0	4.0
22	2.0	3.0	3.0	4.0	4.0	4.0	4.0	4.0
23	2.0	2.0	3.0	4.0	4.0	4.0	4.0	4.0
24	2.0	2.0	3.0	4.0	4.0	4.0	4.0	4.0
25	2.0	3.0	4.0	4.0	4.0	4.0	4.0	5.0
26	2.0	3.0	3.0	4.0	4.0	4.0	4.0	4.0
27	2.0	3.0	3.0	4.0	4.0	4.0	4.0	5.0
28	2.0	3.0	3.0	4.0	4.0	4.0	4.0	4.0
29	2.0	2.0	3.0	4.0	4.0	4.0	4.0	4.0
30	3.0	3.0	3.0	4.0	4.0	4.0	4.0	4.0
<b>Mean</b>	<b>2.73</b>	<b>3.27</b>	<b>3.63</b>	<b>4.07</b>	<b>3.97</b>	<b>4.03</b>	<b>4.10</b>	<b>4.27</b>
<b>SD</b>	<b>0.58</b>	<b>0.64</b>	<b>0.56</b>	<b>0.45</b>	<b>0.49</b>	<b>0.41</b>	<b>0.48</b>	<b>0.58</b>
	<b>1<sup>st</sup> month</b>				<b>2<sup>nd</sup> month</b>			
<b>Min</b>	2.75				3.00			
<b>Max</b>	4.50				5.00			
<b>Mean</b>	3.43				4.09			
<b>SD</b>	0.46				0.44			
<b>Median</b>	3.50				4.00			
<b>Z1</b>	4.565*							
<b>p1</b>	<0.001*							

Z<sub>1</sub>: Z for Wilcoxon signed ranks test

p<sub>1</sub>: p value for Wilcoxon signed ranks test for comparing between 1<sup>st</sup> and 2<sup>nd</sup> month

\*: Statistically significant at p ≤ 0.05

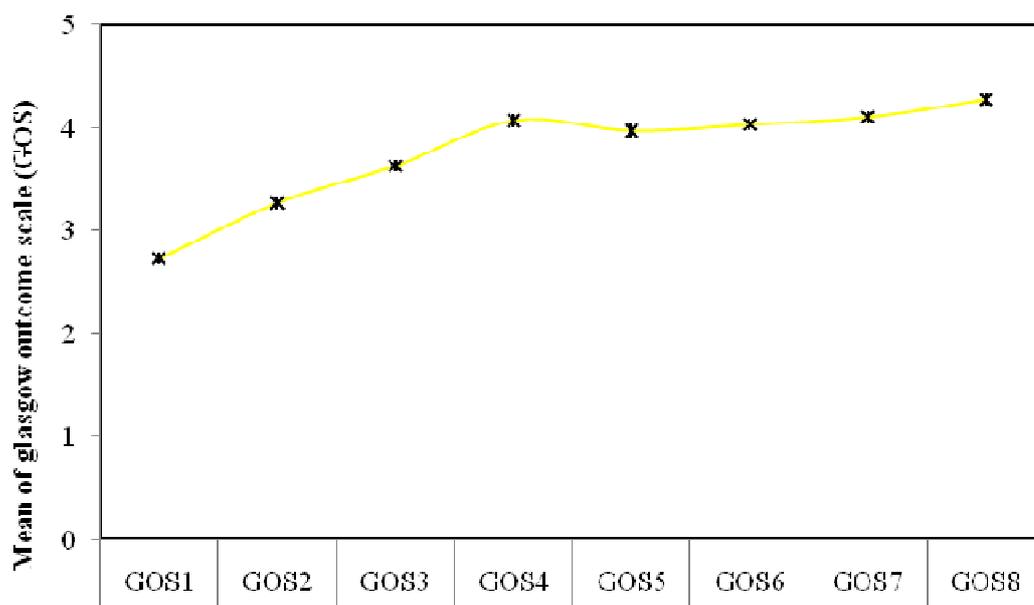
**Table (40): Comparison between the First four weeks and Second four weeks according to The Glasgow Outcome Scale (GOS) in Group II.**

Cases	First four weeks				Second four weeks			
	GOS1	GOS2	GOS3	GOS4	GOS5	GOS6	GOS7	GOS8
1	3.0	3.0	3.0	3.0	4.0	4.0	4.0	4.0
2	3.0	3.0	3.0	3.0	3.0	4.0	5.0	5.0
3	3.0	3.0	3.0	3.0	4.0	4.0	4.0	5.0
4	3.0	3.0	3.0	3.0	3.0	4.0	4.0	5.0
5	3.0	3.0	3.0	3.0	3.0	3.0	4.0	4.0
6	3.0	3.0	3.0	3.0	4.0	4.0	4.0	5.0
7	3.0	3.0	3.0	4.0	4.0	4.0	4.0	5.0
8	3.0	4.0	4.0	4.0	4.0	4.0	5.0	5.0
9	3.0	3.0	3.0	3.0	3.0	4.0	4.0	5.0
10	3.0	3.0	3.0	3.0	3.0	3.0	4.0	4.0
11	2.0	3.0	3.0	4.0	4.0	4.0	4.0	4.0
12	3.0	3.0	3.0	3.0	4.0	4.0	4.0	5.0
13	3.0	3.0	3.0	3.0	4.0	4.0	4.0	5.0
14	3.0	3.0	3.0	4.0	4.0	4.0	5.0	5.0
15	3.0	3.0	3.0	3.0	4.0	4.0	4.0	5.0
16	3.0	3.0	3.0	3.0	3.0	4.0	4.0	4.0
17	2.0	3.0	3.0	3.0	4.0	4.0	4.0	5.0
18	3.0	3.0	3.0	3.0	3.0	3.0	4.0	4.0
19	3.0	3.0	3.0	4.0	4.0	4.0	4.0	5.0
20	3.0	3.0	3.0	3.0	3.0	3.0	4.0	4.0
21	3.0	3.0	3.0	3.0	4.0	4.0	4.0	4.0
22	2.0	3.0	3.0	3.0	3.0	4.0	4.0	4.0
23	3.0	3.0	3.0	3.0	4.0	4.0	5.0	5.0
24	3.0	3.0	4.0	4.0	4.0	4.0	5.0	5.0
25	3.0	3.0	3.0	3.0	3.0	4.0	4.0	4.0
26	3.0	3.0	3.0	3.0	4.0	4.0	5.0	5.0
27	3.0	3.0	3.0	3.0	4.0	4.0	4.0	4.0
28	3.0	3.0	3.0	4.0	4.0	4.0	5.0	5.0
29	3.0	3.0	3.0	4.0	4.0	4.0	4.0	5.0
30	3.0	3.0	3.0	3.0	4.0	4.0	4.0	4.0
<b>Mean</b>	<b>2.90</b>	<b>3.03</b>	<b>3.07</b>	<b>3.27</b>	<b>3.67</b>	<b>3.87</b>	<b>4.23</b>	<b>4.60</b>
<b>SD</b>	<b>0.31</b>	<b>0.18</b>	<b>0.25</b>	<b>0.45</b>	<b>0.48</b>	<b>0.35</b>	<b>0.43</b>	<b>0.50</b>
	<b>1<sup>st</sup> month</b>				<b>2<sup>nd</sup> month</b>			
<b>Min</b>	2.75				3.50			
<b>Max</b>	3.75				4.50			
<b>Mean</b>	3.07				4.09			
<b>SD</b>	0.20				0.32			
<b>Median</b>	3.00				4.25			
<b>Z<sub>1</sub></b>	4.832*							
<b>p<sub>1</sub></b>	<0.001*							

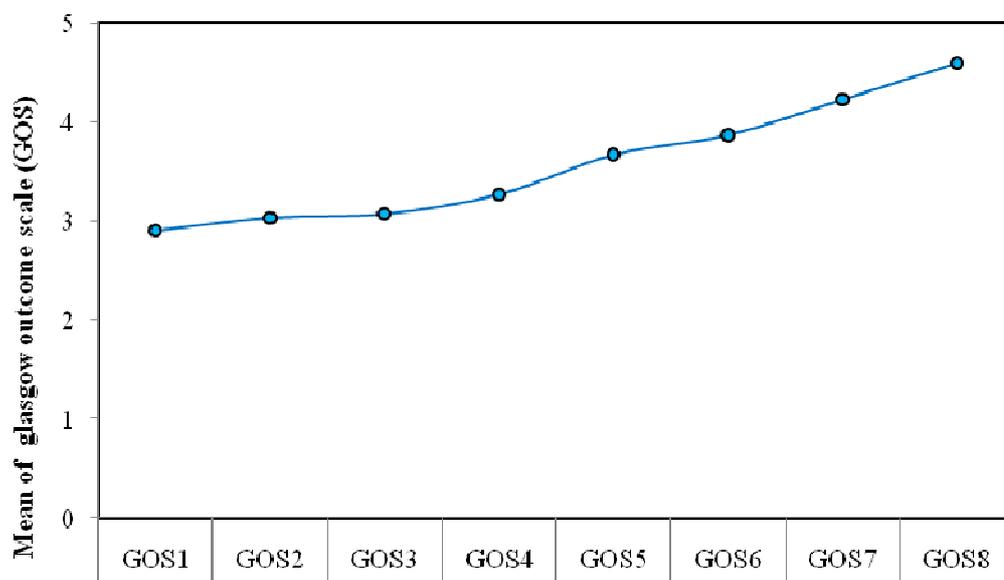
Z<sub>1</sub>: Z for Wilcoxon signed ranks test

p<sub>1</sub>: p value for Wilcoxon signed ranks test for comparing between 1<sup>st</sup> and 2<sup>nd</sup> month

\*: Statistically significant at p ≤ 0.05



**Figure (25):** Distribution of studied cases according to The Glasgow Outcome Scale (GOS) in Group I (Amantadine first 4 weeks, placebo second 4 weeks).



**Figure (26):** Distribution of studied cases according to The Glasgow Outcome Scale (GOS) in Group II (placebo first 4 weeks, Amantadine second 4 weeks).

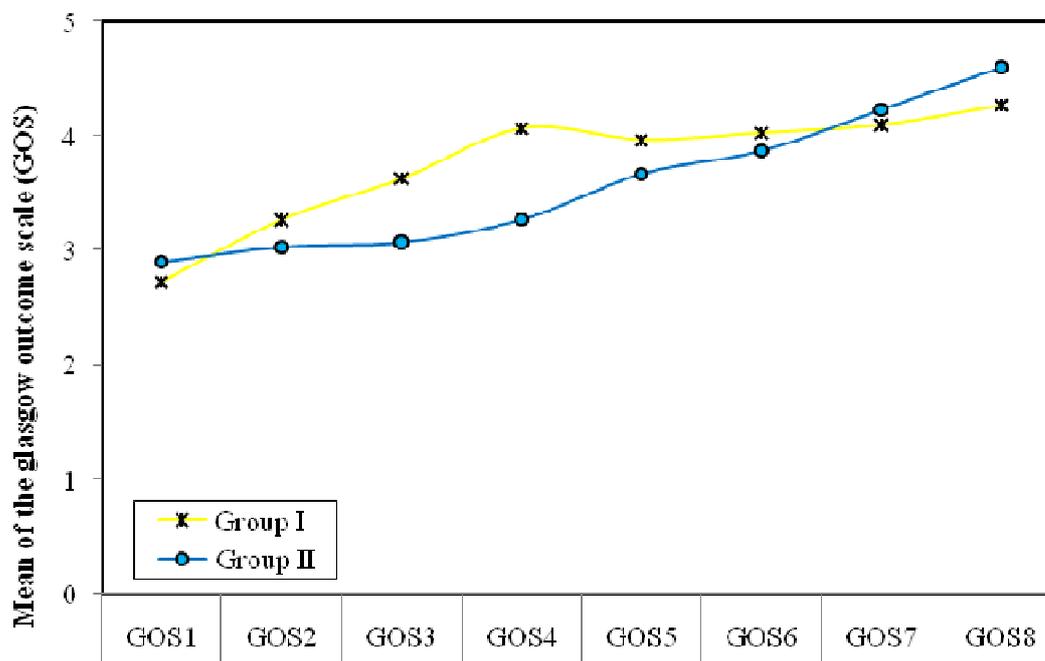
**Table (41): Comparison between the two studied groups in the 1st and 2nd month according to The Glasgow Outcome Scale (GOS).**

GOS	Group I (n=30)	Group II (n=30)	Z	p
<b>1<sup>st</sup> month</b>				
Min. – Max.	2.75 – 4.50	2.75 – 3.75	3.308*	0.001*
Mean ± SD.	3.43 ± 0.46	3.07 ± 0.20		
Median	3.50	3.0		
<b>2<sup>nd</sup> month</b>				
Min. – Max.	3.0 – 5.0	3.50 – 4.50	0.492	0.623
Mean ± SD.	4.09 ± 0.44	4.09 ± 0.32		
Median	4.0	4.25		

Z: Z for Mann Whitney test

p: p value for Mann Whitney test for comparing between the two studied groups

\*: Statistically significant at  $p \leq 0.05$



**Figure (27): Comparison between the two studied groups according to The Glasgow Outcome Scale (GOS).**

#### **4. Comparison between the studied groups according to The Galveston Orientation and Amnesia Test (GOAT).**

There was an improvement in the GOAT scores of 28.97 points from  $45.33 \pm \text{SD } 30.36$  to  $74.30 \pm \text{SD } 11.12$  in group I on the active drug during the first 4 weeks of treatment in comparison to only 4.33 points from  $76.10 \pm \text{SD } 10.42$  to  $80.43 \pm \text{SD } 9.46$  in the second 4-week period when they were on the placebo, There was statically significant difference between 1st and 2nd month  $p < 0.001$  (table 42, figure 28).

In group II (active drug second 4 weeks), there was an improvement in the GOAT of 12.86 points from  $57.67 \pm \text{SD } 6.49$  to  $70.53 \pm \text{SD } 4.48$  spontaneously in the first 4 weeks, but the group gained additional 13.76 points of recovery from  $76.37 \pm \text{SD } 4.07$  to  $90.13 \pm \text{SD } 4.05$  while on the active drug between the 5th week and the 8th week, There was statically significant difference between 1st and 2nd month  $p < 0.001$  (table 43, figure 29).

When comparing the amount of change between the groups, there was no statistical difference in the recovery within the first 4 weeks between group I (on active drug) versus group II (placebo)  $p = 0.220$  but statistically significant amount of change during the second 4-week between group I (placebo) and group II (on active drug) ( $P = 0.011$ ) (table 44, figure 30).

**Table (42): Comparison between the First four weeks and Second four weeks according to The Galveston Orientation and Amnesia Test (GOAT) in Group I**

Cases	First four weeks				Second four weeks			
	GOAT1	GOAT2	GOAT3	GOAT4	GOAT5	GOAT6	GOAT7	GOAT8
1	48.0	66.0	76.0	78.0	78.0	77.0	79.0	79.0
2	47.0	64.0	77.0	78.0	78.0	78.0	78.0	79.0
3	66.0	70.0	73.0	75.0	76.0	77.0	76.0	80.0
4	70.0	75.0	78.0	80.0	85.0	86.0	86.0	85.0
5	60.0	77.0	76.0	80.0	82.0	85.0	85.0	86.0
6	65.0	69.0	77.0	76.0	80.0	82.0	82.0	85.0
7	40.0	45.0	55.0	67.0	69.0	69.0	73.0	72.0
8	72.0	75.0	80.0	85.0	87.0	87.0	85.0	90.0
9	70.0	75.0	75.0	80.0	85.0	89.0	90.0	92.0
10	48.0	66.0	76.0	78.0	78.0	77.0	79.0	81.0
11	79.0	80.0	90.0	95.0	96.0	96.0	98.0	98.0
12	70.0	75.0	80.0	85.0	85.0	89.0	89.0	90.0
13	66.0	70.0	76.0	76.0	80.0	80.0	82.0	83.0
14	68.0	70.0	75.0	79.0	79.0	80.0	80.0	81.0
15	50.0	56.0	70.0	75.0	75.0	80.0	80.0	81.0
16	65.0	70.0	75.0	76.0	80.0	82.0	84.0	85.0
17	66.0	70.0	75.0	79.0	79.0	82.0	83.0	83.0
18	70.0	75.0	78.0	79.0	79.0	82.0	83.0	83.0
19	40.0	55.0	60.0	72.0	74.0	75.0	75.0	76.0
20	-10.0	20.0	36.0	39.0	40.0	40.0	42.0	43.0
21	-2.0	10.0	50.0	70.0	72.0	73.0	75.0	75.0
22	60.0	66.0	70.0	72.0	73.0	74.0	75.0	75.0
23	-20.0	12.0	16.0	40.0	50.0	57.0	65.0	67.0
24	-12.0	10.0	30.0	70.0	72.0	74.0	75.0	78.0
25	66.0	70.0	75.0	80.0	81.0	84.0	85.0	86.0
26	-10.0	22.0	50.0	65.0	66.0	70.0	73.0	75.0
27	40.0	55.0	67.0	76.0	77.0	79.0	79.0	80.0
28	60.0	67.0	75.0	78.0	79.0	80.0	81.0	85.0
29	-6.0	48.0	60.0	68.0	69.0	72.0	74.0	76.0
30	34.0	38.0	60.0	78.0	79.0	80.0	82.0	84.0
<b>Mean</b>	<b>45.33</b>	<b>57.37</b>	<b>67.03</b>	<b>74.30</b>	<b>76.10</b>	<b>77.87</b>	<b>79.10</b>	<b>80.43</b>
<b>SD</b>	<b>30.36</b>	<b>21.76</b>	<b>16.47</b>	<b>11.12</b>	<b>10.42</b>	<b>10.20</b>	<b>9.40</b>	<b>9.46</b>
	<b>1<sup>st</sup> month</b>				<b>2<sup>nd</sup> month</b>			
<b>Min</b>	12.00				41.25			
<b>Max</b>	86.00				97.00			
<b>Mean</b>	61.01				78.38			
<b>SD</b>	19.09				9.78			
<b>Median</b>	68.50				79.50			
<b>Z1</b>	4.785*							
<b>p1</b>	<0.001*							

Z<sub>1</sub>: Z for Wilcoxon signed ranks test

p<sub>1</sub>: p value for Wilcoxon signed ranks test for comparing between 1<sup>st</sup> and 2<sup>nd</sup> month

\*: Statistically significant at p ≤ 0.05

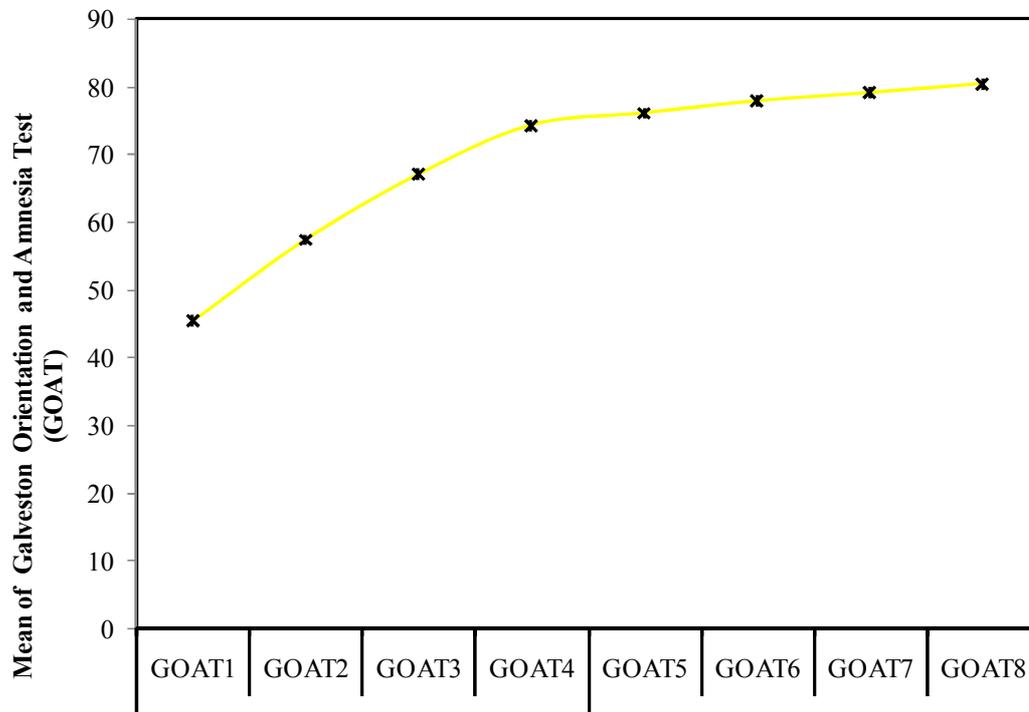
**Table (43): Comparison between the First four weeks and Second four weeks according to The Galveston Orientation and Amnesia Test (GOAT) in Group II.**

Cases	First four weeks				Second four weeks			
	GOAT1	GOAT2	GOAT3	GOAT4	GOAT5	GOAT6	GOAT7	GOAT8
1	50.0	55.0	62.0	65.0	70.0	77.0	82.0	90.0
2	53.0	60.0	67.0	69.0	76.0	79.0	83.0	89.0
3	54.0	61.0	65.0	74.0	82.0	85.0	91.0	93.0
4	60.0	67.0	72.0	75.0	79.0	82.0	84.0	90.0
5	63.0	66.0	70.0	72.0	78.0	81.0	85.0	89.0
6	60.0	63.0	66.0	71.0	75.0	79.0	82.0	91.0
7	68.0	71.0	76.0	79.0	81.0	86.0	90.0	93.0
8	66.0	68.0	73.0	75.0	79.0	81.0	83.0	92.0
9	50.0	64.0	67.0	73.0	79.0	80.0	86.0	93.0
10	68.0	70.0	73.0	75.0	79.0	81.0	85.0	87.0
11	56.0	60.0	65.0	69.0	73.0	77.0	79.0	81.0
12	58.0	61.0	64.0	69.0	73.0	79.0	83.0	88.0
13	55.0	60.0	66.0	69.0	73.0	76.0	79.0	84.0
14	57.0	65.0	70.0	75.0	80.0	85.0	89.0	92.0
15	60.0	64.0	66.0	70.0	75.0	79.0	82.0	89.0
16	54.0	57.0	59.0	66.0	73.0	79.0	83.0	86.0
17	58.0	61.0	63.0	73.0	79.0	82.0	86.0	92.0
18	50.0	59.0	64.0	69.0	76.0	82.0	89.0	91.0
19	62.0	66.0	68.0	71.0	82.0	86.0	89.0	93.0
20	70.0	73.0	76.0	79.0	81.0	86.0	92.0	96.0
21	58.0	61.0	63.0	68.0	76.0	81.0	86.0	94.0
22	51.0	57.0	63.0	66.0	71.0	77.0	79.0	83.0
23	52.0	56.0	60.0	66.0	71.0	76.0	81.0	89.0
24	67.0	68.0	71.0	74.0	80.0	86.0	92.0	96.0
25	62.0	57.0	59.0	61.0	68.0	72.0	79.0	80.0
26	43.0	52.0	59.0	62.0	73.0	79.0	82.0	91.0
27	60.0	64.0	66.0	70.0	78.0	85.0	89.0	92.0
28	61.0	67.0	69.0	72.0	79.0	82.0	89.0	94.0
29	54.0	61.0	65.0	74.0	82.0	85.0	91.0	93.0
30	50.0	55.0	62.0	65.0	70.0	77.0	82.0	93.0
<b>Mean</b>	<b>57.67</b>	<b>62.30</b>	<b>66.30</b>	<b>70.53</b>	<b>76.37</b>	<b>80.73</b>	<b>85.07</b>	<b>90.13</b>
<b>SD</b>	<b>6.49</b>	<b>5.17</b>	<b>4.76</b>	<b>4.48</b>	<b>4.07</b>	<b>3.65</b>	<b>4.15</b>	<b>4.05</b>
	<b>1<sup>st</sup> month</b>				<b>2<sup>nd</sup> month</b>			
<b>Min</b>	54.00				74.75			
<b>Max</b>	74.50				88.75			
<b>Mean</b>	64.20				83.08			
<b>SD</b>	4.87				3.69			
<b>Media n</b>	63.50				83.50			
<b>Z1</b>	4.783*							
<b>p1</b>	<0.001*							

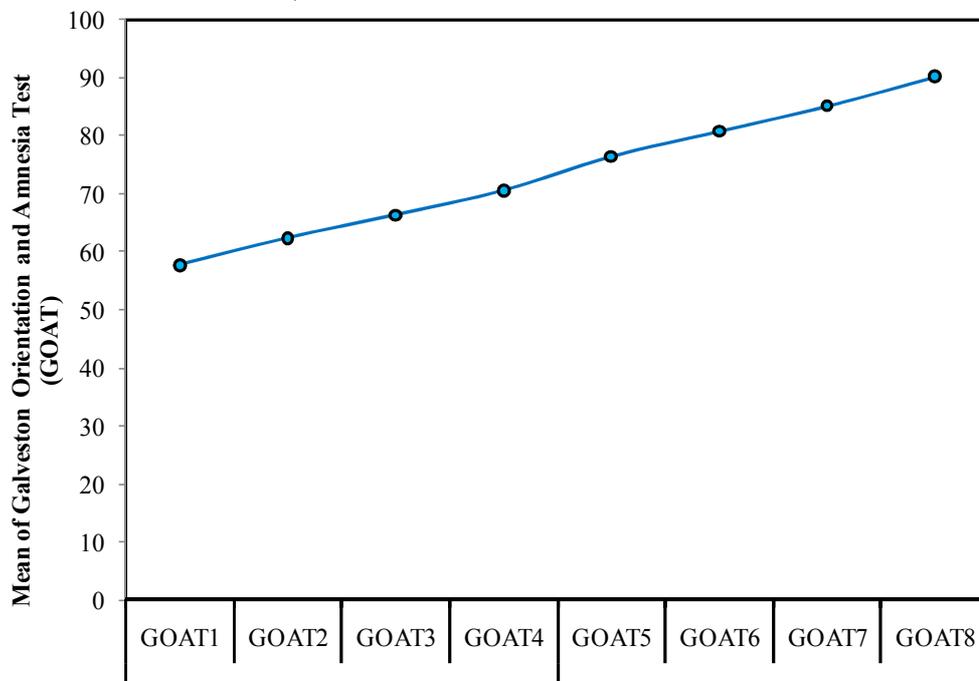
Z<sub>1</sub>: Z for Wilcoxon signed ranks test

p<sub>1</sub>: p value for Wilcoxon signed ranks test for comparing between 1<sup>st</sup> and 2<sup>nd</sup> month

\*: Statistically significant at p ≤ 0.05



**Figure (28):** Distribution of studied cases according to The Galveston Orientation and Amnesia Test (GOAT) in Group I (Amantadine first 4 weeks, placebo second 4 weeks).



**Figure (29):** Distribution of studied cases according to The Galveston Orientation and Amnesia Test (GOAT) in Group II (placebo first 4 weeks, Amantadine second 4 weeks).

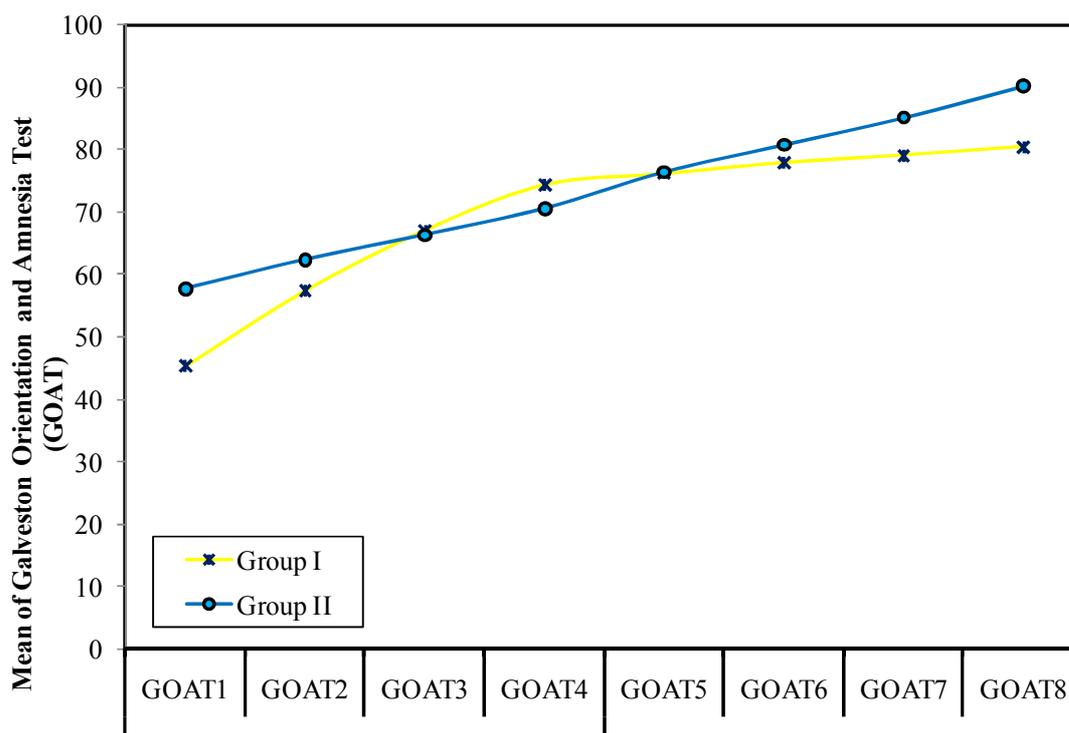
**Table (44): Comparison between the two studied groups in the 1st and 2nd month according to The Galveston Orientation and Amnesia Test (GOAT).**

GOAT	Group I (n=30)	Group II (n=30)	Z	p
<b>1<sup>st</sup> month</b>				
Min. – Max.	12.0 – 86.0	54.0 – 74.50	1.227	0.220
Mean ± SD.	61.01 ± 19.09	64.20 ± 4.87		
Median	68.50	63.50		
<b>2<sup>nd</sup> month</b>				
Min. – Max.	41.25 – 97.0	74.75 – 88.75	2.552*	0.011*
Mean ± SD.	78.38 ± 9.78	83.08 ± 3.69		
Median	79.50	83.50		

Z: Z for Mann Whitney test

p: p value for Mann Whitney test for comparing between the two studied groups

\*: Statistically significant at  $p \leq 0.05$



**Figure(30): Comparison between the studied groups according to The Galveston Orientation and Amnesia Test (GOAT).**

## VI Co-Morbidity:

### 1. Long standing complication of trauma patients in the ICU

In the present study patients suffered from complications in ICU as ventilator associated pneumonia (VAP), bed sores, Sepsis, Disseminated intravascular coagulation (DIC), Renal impairment, pulmonary embolism(PE).

There was no statically significant difference between the two groups  $P=0.542$ ,  $P=0.542$ ,  $P=0.519$ ,  $^{FE}p=1.000$ ,  $^{FE}p=1.000$ ,  $^{FE}p=1.000$  respectively (table 45, figure 31)

### 2. Side effects related to amantadine use

Comparison between two groups according to Side effects related to amantadine use as Insomnia, Vivid dreams, Anorexia, Hallucinations, Agitation, Delirium, Depression, Seizure and Livido reticularis (lace-like purplish discoloration of the skin) there was no statically significant difference between the two groups  $^{FE}p=0.706$ ,  $^{FE}p=1.000$ ,  $^{FE}p=0.612$ ,  $^{FE}p=1.000$ ,  $^{FE}p=1.000$ ,  $^{FE}p=1.000$ ,  $^{FE}p=1.000$ ,  $^{FE}p=1.000$  respectively also There was no statistically significant difference between the 2 groups for patients not suffering from any complications  $p=0.118$  (table 46,figure 32).

### 3. Days of ICU stay

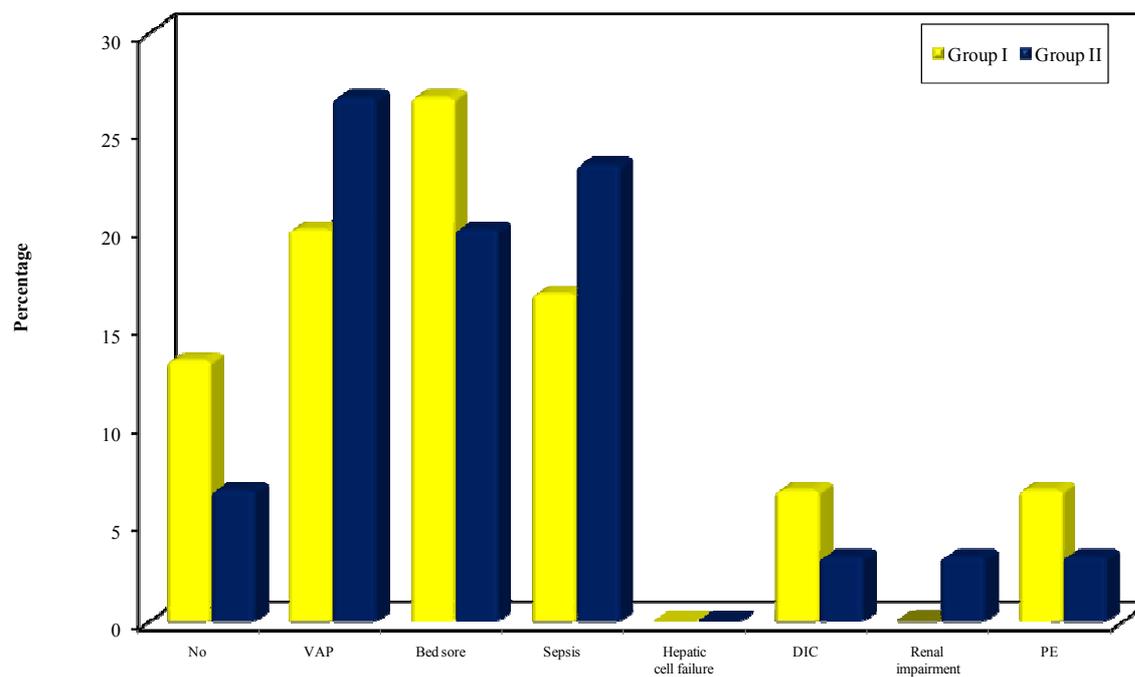
Comparison between two groups according to days in intensive care unit there is statistically significant difference between the 2 groups as the mean of group I is  $28.13 \pm SD6.10$  and group II is  $36.43 \pm SD11.61$   $p=0.001$ (table 47,figure 33).

**Table (45): Comparison between the two studied groups according to Complications in ICU.**

Complications in ICU	Group I (N = 30)		Group II (N = 30)		$\chi^2$	p
	No	%	No	%		
No	4	13.3	2	6.7	0.741	$^{FE}p=0.385$
VAP	6	20.0	8	26.7	0.373	0.542
Bed Sores	8	26.7	6	20.0	0.373	0.542
Sepsis	5	16.7	7	23.3	0.417	0.519
Hepatic cell failure	0	0.0	0	0.0	-	-
DIC	2	6.7	1	3.3	0.351	$^{FE}p=1.000$
Renal impairment	0	0.0	1	3.3	1.017	$^{FE}p=1.000$
PE	2	6.7	1	3.3	0.351	$^{FE}p=1.000$

$\chi^2$ : Chi square test

FE: Fisher Exact test



**Figure (31):** Comparison between the two studied groups according to complications in ICU.

Table (46): Comparison between the two studied groups according to Side effects related to amantadine use.

Complications due to amantadine	Group I (N = 30)		Group II (N = 30)		$\chi^2$	p
	No	%	No	%		
No	10	33.3	16	53.3	2.443	0.118
Insomnia	5	16.7	3	10.0	0.557	<sup>FE</sup> p=0.706
Vivid dreams	1	3.3	0	0.0	1.017	<sup>FE</sup> p=1.000
Anorexia	3	10.0	1	3.3	1.071	<sup>FE</sup> p=0.612
Hallucinations	4	13.3	3	10.0	0.162	<sup>FE</sup> p=1.000
Agitation	2	6.7	1	3.3	0.351	<sup>FE</sup> p=1.000
Delirium	2	6.7	3	10.0	0.218	<sup>FE</sup> p=1.000
Depression	2	6.7	1	3.3	0.162	<sup>FE</sup> p=1.000
Seizure	1	3.3	2	6.7	0.351	<sup>FE</sup> p=1.000
Livido reticularis	0	0.0	0	0.0	-	-

$\chi^2$ : Chi square test  
 FE: Fisher Exact test

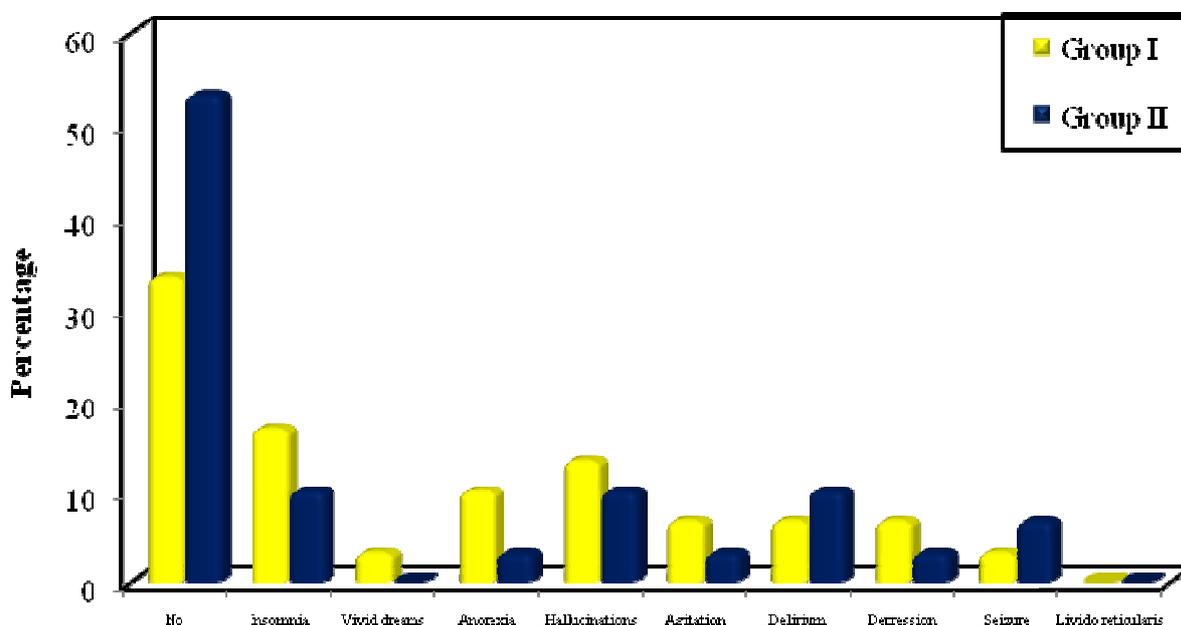


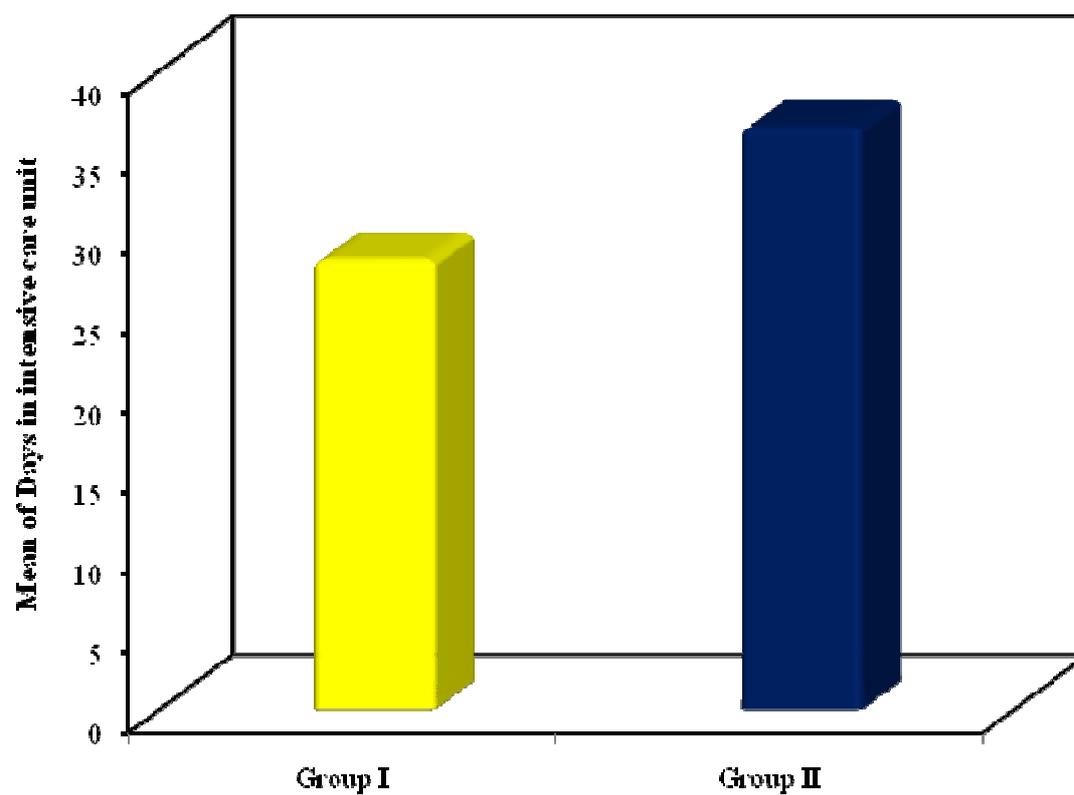
Figure (32): Comparison between the two studied groups according to complications due to amantadine.

**Table (47): Comparison between the two studied groups according to days in intensive care unit.**

Cases	Days in intensive care unit	
	Group I (n=30)	Group II (n=30)
1	19	43
2	28	38
3	25	34
4	23	46
5	28	50
6	34	56
7	33	34
8	28	22
9	32	52
10	27	54
11	22	33
12	36	43
13	21	27
14	33	34
15	27	30
16	34	16
17	29	19
18	25	45
19	28	52
20	37	39
21	20	47
22	36	44
23	31	36
24	35	37
25	36	40
26	32	27
27	20	18
28	16	17
29	18	38
30	31	22
<b>Min</b>	16.0	16.0
<b>Max</b>	37.0	56.0
<b>Mean</b>	28.13	36.43
<b>SD</b>	6.10	11.61
<b>Median</b>	28.0	37.50
<b>t</b>		3.467*
<b>p</b>		0.001*

t: Student t-test

\*: Statistically significant at  $p \leq 0.05$



**Figure (33):** Comparison between the two studied groups according to days in intensive care unit.