

## Iron Presented as Food (Sun Active Iron) versus Pharmaceutical Iron Therapy (Ferric Hydroxide Polymaltose Complex) For Treatment of Iron Deficiency Anemia in Children

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**Abstract: Background:** iron deficiency is considered the most common nutritional deficiency worldwide, and the most significant negative consequence of iron deficiency is iron deficiency anemia (IDA). Treatments of IDA may include dietary changes and supplements. **Methodology:** The study had been conducted on 100 children diagnosed as iron deficiency anemia, their age from 1-5 years, classified into two groups: group one included 50 patients treated by essential iron micronized dispersible ferric pyrophosphate; group two included 50 patients treated by oral ferric hydroxide polymaltose complex for three months. Hb, RBCS indices and iron profile were obtained from all participants. **Results:** The mean of Hb and RBCS indices were significantly improved in the two groups after three months of treatment compared to their baseline. As regard iron profile, it has been found that the two groups show also improvement in parameters after treatment, but with no significant difference between them. **Conclusion:** The two groups showed improvement in all parameters of anemia and both treatment regimens are equally effective in treatment of iron deficiency anemia.

[Esam eldeen Gadelrab, Sayed Ali, Mohammed Mansour and Asmaa Abdelall. **Iron Presented as Food (Sun Active Iron) versus Pharmaceutical Iron Therapy (Ferric Hydroxide Polymaltose Complex) For Treatment of Iron Deficiency Anemia in Children.** *N Y Sci J* 2018;11(8):51-54]. ISSN 1554-0200 (print); ISSN 2375-723X (online). <http://www.sciencepub.net/newyork>. 7. doi: [10.7537/marsnys110818.07](https://doi.org/10.7537/marsnys110818.07).

**Keywords:** Iron deficiency anemia; treatment; Micronized dispersible ferric pyrophosphate, Ferric Hydroxide Polymaltose Complex, Hb, iron profile

### 1. Introduction

Iron deficiency is the most common cause of anemia. There are different types of anemia including hemorrhagic anemia due to excessive loss of blood, hemolytic anemia due to red blood cell destruction and hematopoietic anemia due to less production of RBCS. There are many causes of anemia but the most common cause is iron deficiency (Ullah I et al, and 2013).

Iron deficiency anemia leads to weakness, poor physical growth, and a compromised immune system, decreasing the ability to fight infections and increasing morbidity and is also thought to impair cognitive performance and delay psychomotor development (Horton and Ross, 2003).

Treatment for iron-deficiency anemia will depend on its cause and severity. Severe iron- deficiency anemia may require iron injections, or intravenous (IV) iron therapy. The goals of treating iron-deficiency anemia are to treat its underlying causes and to restore normal levels of red blood cells, hemoglobin, and iron (Am Fam Physician, 2013).

Molecules are a micronized and microencapsulated ferric pyrophosphate produced by micro dispersion technology (nanao technology) to deliver highly bioavailable, less reactive, taste free (non-metallic), dispersible (in liquids), relatively high gastric tolerant with negligible side effects for use in almost all kinds of foods fortification such as

beverage, dairy and all other food applications. Due to its high bioavailability (>90%) and high gastric tolerance, micronized dispersible ferric pyrophosphate has been used in number of food supplements targeting all age group (Taiyo, 2004).

### 2. Patients and Methods:

The study design was an open-label, randomized controlled clinical trial that was conducted on 100 patients from Fayoum governorate residents, aged from 1-5 years old, and diagnosed as iron deficiency anemia. Patients classified into two groups. Group one: Included 50 patients supplements with essential iron micronized dispersible ferric pyrophosphate (sun active iron) in the form of a 350 gm jar of liquid chocolate. At dose 7.5mg twice a day to children below four years old and 15mg twice a day to children above four years old, for three months. Group two: Included 50 patients who taking oral iron therapy in the form of ferric hydroxide polymaltose complex 50 mg/5ml at dose of 6mg/kg/day for three months.

All the patients were subjected to full history taking focusing on nutritional history: Type of feeding: breast feeding, artificial feeding, vitamin supplementation, weaning: timing, type of food and amount. This was followed by general examination including head and neck, color (pallor), and extremities. Local Examination including: cardiac, chest, abdominal and neurological examination.

Laboratory Investigations including: Complete blood count, Iron profile: serum Iron, serum ferritin, TIBC and transferrin saturation.

Complete blood count and iron profile were done in the beginning of the study and repeated at the end of study (after three months).

#### Statistical Analysis:

Data management was performed using the statistical package for social sciences (version 15.0; SPSS inc., Chicago, IL, USA). Compute standard descriptive statistics (e.g., mean standard deviation) was used to summarize the data. Nominal data was analyzed using simple X2test, while independent sample T-test procedure was used to compare means for two groups of cases for more than two groups, data was evaluated with one-way analysis of variance

(ANOVA). A probability value (p value) less than 0.05 was considered significant.

This study was reviewed by the Faculty of Medicine Research Ethical Committee.

The researcher was informed the participants about the objectives of the study, the examination and investigation that were done. Also the confidentiality of their information and their right not participated in the study.

### 3. Results

Our study included 100 patients diagnosed as iron deficiency anemia, classified into two groups, group one included 50 patients treated by essential iron micronized dispersible ferric pyrophosphate, group two included 50 patients treated by oral ferric hydroxide polymaltose complex for three months.

**Table1: Socio-demographic characteristics of children in the study groups**

Variable	Group 1 (50)	Group 2 (50)	P-value
	Mean $\pm$ SD		
Age (Months)	34.9 $\pm$ 18.2	32.5 $\pm$ 17.9	0.522
Variable	N (%)		P-value
Sex:			
Male	24 (48.0)	29 (58.0)	0.316
Female	26 (52.0)	21 (42.0)	
Residence:			
Urban	21 (42.0)	18 (36.0)	0.539
Rural	29 (58.0)	32 (64.0)	

**Table 2: Difference in Hb and RBCS indices before intervention in relation to the study groups**

Variable	Group 1 (50)	Group 2 (50)	P-value
	Mean $\pm$ SD		
HB	9.77 $\pm$ 1.09	9.57 $\pm$ 1.76	0.508
MCV	65.29 $\pm$ 5.67	66.89 $\pm$ 9.08	0.295
MCH	20.06 $\pm$ 2.64	19.98 $\pm$ 3.55	0.898
Reticulocytes	1.31 $\pm$ 0.53	1.25 $\pm$ 0.38	0.517
RDW	16.89 $\pm$ 2.70	17.14 $\pm$ 3.01	0.673

**Table 3: Difference in Hb and RBCS indices after intervention of iron therapy in relation to the study groups**

Variable	Group 1 (50)	Group 2 (50)	P-value
	Mean $\pm$ SD		
HB	10.94 $\pm$ 1.05	11.13 $\pm$ 1.44	0.453
MCV	69.62 $\pm$ 6.09	70.54 $\pm$ 9.03	0.552
MCH	22.37 $\pm$ 2.23	22.34 $\pm$ 3.55	0.552
RDW	15.52 $\pm$ 2.77	16.33 $\pm$ 3.45	0.199

**Table 4: Differences in iron profile before intervention in relation to the study groups**

Variable	Group 1 (50)	Group 2 (50)	P-value
	Mean $\pm$ SD		
Iron	40.74 $\pm$ 19.73	38.12 $\pm$ 21.36	0.525
TIBC	360.56 $\pm$ 93.07	348.39 $\pm$ 71.81	0.196
Ferritin	8.79 $\pm$ 4.94	11.11 $\pm$ 7.15	0.062
Transferrin saturation	12.36 $\pm$ 6.70	11.92 $\pm$ 7.29	0.757

**Table 5: Differences in iron profile after intervention in relation to the study groups**

Variable	Group 1 (50)	Group 2 (50)	P-value
	Mean $\pm$ SD		
Iron	62.58 $\pm$ 23.62	61.72 $\pm$ 22.81	0.690
TIBC	317.74 $\pm$ 73.15	301.54 $\pm$ 65.81	0.245
Ferritin	33.64 $\pm$ 12.34	33.82 $\pm$ 16.96	0.952
Transferrin saturation	22.94 $\pm$ 11.87	20.59 $\pm$ 9.67	0.283

**Table 6: Improvement in anemia in the study groups**

Variable	Group 1	Group 2	P-value
	N (%)		
Improved	31 (62.0)	35 (70.0)	0.211
Not well improved	19 (38.0)	15 (30.0)	

#### 4. Discussion

In the present study there is no significant difference between the two groups as regards the mean of socio-demographic characteristics, anthropometric measurements, nutritional history, developmental history, iron supplementation, and the clinical data.

Before treatment, in the present study both groups showed decline below the normal level in measurement of parameters of IDA (Hb, RBCS indices, and iron profile), with no statistically significant difference between them.

After treatment for three months by food supplementation in group one: the rate of anemia regarding the hemoglobin level, showed significant difference before ( $9.77 \pm 1.09$ ) and after treatment ( $10.94 \pm 1.05$ ) ml/dl % with p-value  $< 0.0001$ .

Out of the 50 patients received food supplementation with iron in group one, only 31 patients improved from anemia.

After treatment for three months by oral iron therapy in group two: Regarding the hemoglobin level showed significant difference before ( $9.57 \pm 1.76$ ) and after treatment ( $11.13 \pm 1.44$ ) ml/dl % with p-value  $< 0.0001$ .

Out of the 50 patients received oral iron therapy in group two, only 35 patients improved from anemia.

Our results agreed with (Imelda Angeles et al, 2010) who studied Basal hemoglobin levels in both the fortified and nonfortified groups suffering from IDA, Group 1 received the fortified juice, Group 2 received the nonfortified juice for 100 days, The juice drink was fortified with iron (Micronized dispersible ferric pyrophosphate), vitamin A, zinc, vitamin C and lysine. The non-fortified juice was fortified only with vitamin C. Hemoglobin, plasma ferritin were assessed before and after intervention.

Basal hemoglobin levels in both the fortified and nonfortified groups were similar at baseline. At endline, the mean hemoglobin levels in both the fortified and non-fortified groups had significantly increased. However; mean change in the fortified group was significantly higher than the non-fortified group. The rate of anemia in the fortified group significantly reduced from 100% to 13.0%; while in non-fortified group, from 100% at baseline to 39.5% at endline. Basal plasma ferritin levels of the fortified ( $27.6 \mu\text{g/L}$ ) and non-fortified ( $28.8 \mu\text{g/L}$ ) groups were similar at baseline. At endline, significant increases in plasma ferritin levels were achieved by both groups.

Also our results agreed with (Int J Vitam Nutr Res, 2008) who studied 180 randomly selected 6-9-years old anemic children were randomly allocated to three groups in a double-blinded manner: One group received iron-enriched rice (IER) with extruded iron premix rice (IPR) using ferrous sulfate as fortificant (ExFeSO<sub>4</sub>); the second group received IER with extruded IPR using micronized dispersible ferric pyrophosphate (ExFeP80); and the third group received non-fortified rice (Control). These were administered daily for 5 days a week for 6 months. Blood samples were collected at baseline after 3 and 6 months.

At baseline prevalence of anemia in all groups, which was 100%, was significantly reduced to 51%, 54%, and 63% in the ExFeSO<sub>4</sub>, ExFeP80 and Control groups respectively. After 6 months, further significant reductions were observed in the ExFeSO<sub>4</sub> (38%) and ExFeP80 (33%) but remained at 63% in the Control group. Greater, significant increases were also observed in plasma ferritin in the fortified groups than in the Control group from baseline to 6 months. The predictors of change in hemoglobin (Hb) and plasma ferritin were group allocation and basal values.

Our results agreed with **(Beril Yasa et al, 2011)** In a prospective, open-label, 4- month study, 103 children aged >6 months with iron deficiency anemia (IDA) were randomized to IPC once daily or ferrous sulfate twice daily, (both 5mg iron/kg/day). Mean increases in Hb to months 1 and 4 with IPC were  $1.2 \pm 0.9$  g/dL and  $2.3 \pm 1.3$  g/dL, respectively, (both  $P = 0.001$  versus baseline).

In the study of **(Irfan Ullah Marwat et al, 2013)** 150 children of IDA were enrolled and randomized them into two treatment groups; FS and IPC. Efficacy (rise in Hb concentration by  $\geq 2$  gm/dl) after regular use of IPC in adequate dosage for three months was assessed.

Our results agreed with **(Sozmen et al, 2003)** who studied Thirty-seven children (aged 8–168 MS) with IDA were taken into the study. Seventeen children were treated with the ferric hydroxide–polymaltose complex (IPC); twenty children were treated with a ferrous sulfate complex. Fasting blood samples of patients were obtained at baseline, the first and the third month of treatment period. Hemoglobin and iron levels of patients in both groups were higher in the first and third months compared to baseline. Regarding hemoglobin level in group who treated by IPC showed rise from  $(10.0 \pm 0.6)$  to  $(11.6 \pm 1.05)$  and regarding to serum iron level showed rise from  $(23.4 \pm 25.9)$  at baseline to  $(66.6 \pm 26.1)$ mcg/dl at 3 months.

Finally in the present study, by comparison between the two groups, the rate of anemia was significantly reduced from 100% at baseline to 38% at endline in fortified group (group one) and from 100% at baseline to 30% at endline in oral group (group two) regarding the hemoglobin level after three months from treatment. So some time, more time is needed for completion of treating patients with IDA.

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8/25/2018