

# Impact of twice weekly versus daily iron supplementation during pregnancy on maternal and fetal haematological indices: a randomized clinical trial

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أثر التزويد بالحديد مرتين أسبوعياً مقابل مرة يومياً خلال الحمل على المتناسبات الدموية في الأمهات والأجنة: دراسة سريرية معشاة آزيتا كشناسبي، مركان عليزاده

الخلاصة: لا يزال فقر الدم بعوز الحديد شائعاً بوصفه أحد مضاعفات الحمل في جمهورية إيران الإسلامية، على الرغم من التزويد الروتيني اليومي بالحديد. وقد هدفت هذه الدراسة السريرية المعشاة إلى دراسة مدى كفاءة وتحمل التزويد بالحديد مرتين أسبوعياً مقابل مرة يومياً أثناء الحمل. وقد شملت الدراسة ثلاث مئة وسبعين حاملاً تم اختيارهن عشوائياً لتلقي إما جرعة واحدة يومياً أو جرعتين أسبوعياً من التزويد بالحديد أثناء الحمل. ولم يجد الباحثون اختلافاً يُعتدُّ به إحصائياً في مستوى الهيموغلوبين والهيماتوكريت في بداية الحمل وعند الولادة لدى المجموعتين، ولو أن تركيزات الفيريتين عند الولادة كانت أخفض لدى مجموعتي الممرتين بالأسبوع، ولو أن ذلك لم يصل إلى حدود نقص فيريتين الدم (الأقل من 15 ميكروغرام/ لتر) لدى أي من المجموعتين، كما كان معدل تكرار الغثيان والقيء والإمساك أدنى بدرجة يُعتدُّ بها إحصائياً لدى المجموعة التي تتناول الحديد مرتين في الأسبوع. وكان وزن المواليد وطولهم عند ولادتهم أعلى بقدر يُعتدُّ به لدى المجموعة التي تتناول الحديد مرة واحدة يومياً، فإذا لم تكن الأمهات مصابات بفقر الدم، فإن جرعة أصغر من الحديد قد تكون كافية، وقد تقي من مضاعفات فرط الحديد.

ABSTRACT A randomized clinical trial examined the efficiency and tolerability of twice weekly versus daily iron supplementation during pregnancy. A total of 370 pregnant women were randomly assigned to receive either daily or twice weekly iron supplementation during pregnancy. There were no significant differences in initial and delivery haemoglobin and haematocrit levels between the 2 groups. Ferritin concentrations were significantly lower in the twice weekly group at delivery, but hypoferritinaemia (ferritin < 15 µg/L) was not observed in either group. The frequency of nausea, vomiting and constipation were significantly lower in the twice weekly group. Birth weight and length were significantly higher in the daily supplemented group. In non-anaemic mothers, a smaller dose of iron may be sufficient and also might prevent the complications of iron excess.

## Impact d'une prise de complément en fer bihebdomadaire par rapport à une prise quotidienne pendant la grossesse sur des indices hématologiques maternels et fœtaux : une étude clinique randomisée

RÉSUMÉ Une étude clinique randomisée a examiné l'efficacité et l'innocuité d'une prise bihebdomadaire de complément en fer par rapport à une prise quotidienne pendant la grossesse. Au total, 370 femmes enceintes ont été réparties aléatoirement dans un groupe recevant soit une dose quotidienne de complément en fer, soit une dose bihebdomadaire pendant leur grossesse. Aucune différence significative n'a été observée entre les taux d'hémoglobine et d'hématocrite relevés au début de l'étude et ceux analysés à l'accouchement dans les deux groupes. Les concentrations de ferritine étaient nettement inférieures à l'accouchement dans le groupe recevant deux doses par semaine, mais aucun groupe n'a présenté de cas d'hypoferritinémie (ferritine < 15 µg/l). La fréquence des nausées, des vomissements et de la constipation était significativement moindre dans le groupe aux prises bihebdomadaires. Le poids et la taille du fœtus à la naissance étaient significativement supérieurs dans le groupe bénéficiant d'un complément quotidien. Chez les mères non anémiques, une faible dose de fer peut être suffisante et permettrait aussi de prévenir les complications relatives à un excès en fer.

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## Introduction

Despite widespread preventive programmes, iron-deficiency anaemia during pregnancy is still prevalent and is associated with adverse pregnancy outcomes for both mother and newborn [1–4]. Poor client compliance with national iron supplementation protocols because of side-effects, especially gastrointestinal (GI) complications such as nausea, vomiting and constipation, is suggested as one of the main reasons for the inefficiency of these programmes [5]. Several studies indicate that iron absorption could improve if iron supplements were administered intermittently, matched with mucosal regeneration time of the intestine, which in turn diminishes side-effects and enhances compliance rates [1,6]. Interaction of iron with other micronutrients especially zinc, and also the postulated relationship between high-dose iron supplementation and pregnancy complications such as gestational diabetes, preterm labour and low birth weight, suggest that the amount of iron recommended in the current protocol is too high [3,7–10]. A number of researchers propose that weekly iron supplementation is a reasonable alternative to daily supplementation in terms of haematological indices as well as side-effects [2,6,10,11].

The controversy regarding maintaining the effectiveness of iron supplementation when reducing the dose has not been solved yet [1,12]. Although routine daily iron supplementation from the 4th month of pregnancy is a standard part of prenatal care, iron deficiency anaemia is still a commonly reported complication of pregnancy in the Islamic Republic of Iran [13]. The aim of our study was to examine the efficiency and tolerability of twice weekly versus daily iron supplementation during pregnancy in a sample of Iranian women and present an alternative method for preventing iron-deficiency anaemia and improving maternal and fetal outcomes.

## Methods

A randomized clinical trial was carried out at Imam Hospital in Sari, a coastal city in the north of Islamic Republic of Iran.

### Sample

For a significance level of 0.05 and power 90% and to find a 15% difference in the prevalence of side-effects between 2 groups, the number of subjects required in each set was 171. Between February and November 2009, 370 pregnant women were selected at the prenatal clinic of the hospital. Inclusion criteria were: age between 18–35 years, parity < 4, singleton pregnancy, normal body mass index (BMI) (19.8–25 kg/m<sup>2</sup>), haemoglobin 10.5–13.2 g/dL, gestational age 14–20 weeks and no history of high-risk pregnancy, smoking or drug abuse.

### Data collection

The goals and design of the study were explained by a trained midwife to the women and after obtaining verbal consent baseline sociodemographic and reproductive data were collected. Eligible women were randomly assigned to receive either daily iron supplementation (1 × 150 mg ferrous sulfate tablet containing 50 mg elemental iron and 1 × 1 mg folic acid tablet per day) or twice weekly iron supplementation (1 × 150 mg ferrous sulfate tablet containing 50 mg elemental iron and 1 × 1 mg folic acid tablet on Mondays and Thursdays) from week 20 of pregnancy until delivery. Without blinding, random allocation was done according to the day of week a pregnant woman attended the clinic: clients on even days were assigned to the daily group and attendees on odd days were allocated to the twice weekly group. Mothers of both groups received routine care and were followed up until delivery.

Haemoglobin (Hb) and ferritin concentrations were measured at delivery for mothers, and after birth from the cord blood for neonates. Ferrous

sulfate supplements for both groups (Rouz Darou, Tehran) was distributed through primary health care centres and clinics free of charge. Mothers were given a form to record the number of tablets taken and to flag listed side-effects on a daily basis and to return it at monthly and then weekly prenatal visits. All mothers took part in an educational programme on nutrition in pregnancy.

Maternal and paired cord blood Hb values were determined by the cyanmethohaemoglobin method. A complete blood count was done using an automatic cell counter (T890, Coulter) and serum ferritin was assessed by radioimmunoassay (Gamma Counter System, Kontron). The Center for Disease Control (CDC) Standard reference values for Hb (< 10.5 g/dL in the second trimester and < 11 g/dL in the third trimester for anaemia during pregnancy) and ferritin (ferritin < 15 µg/L for iron deficiency) were used.

The study was approved by the ethics committee of Tarbiat Modares University and registered at the Iranian Registry of Clinical trials (Irct ID: IRCT138802131641N4).

### Data analysis

Statistical analysis was done using the chi squared, Mann–Whitney and Kolmogorov–Smirnov tests to compare the daily and twice weekly supplementation groups. The association between primary BMI, total pregnancy weight gain, gestational age at delivery, type of iron supplementation and birth weight was assessed by linear logistic regression model.

## Results

A total of 365 mothers were included in the final analysis of side-effects (173 in the daily group and 192 in the twice weekly group). Two mothers from the daily group were excluded due to unrelated reasons (1 case of preeclampsia-related intrauterine growth retardation which resulted in preterm delivery

before week 34; and 1 case of idiopathic thrombocytopenic purpura). At the time of delivery 168 and 192 maternal Hb values and 131 and 146 maternal ferritin values were available for analysis in the daily and twice weekly groups respectively. A total of 130 and 151 cord blood samples were analysed for Hb and ferritin concentrations respectively from both groups.

The sociodemographic and reproductive characteristics of the studied women are shown in Table 1. The women in the 2 groups did not differ significantly in terms of age, job, education, parity, BMI or baseline Hb concentration. The mean age of mothers was 26.3 (SD 4.1) years and the mean years of formal education were 9.1 (SD 3.5) years. Most of the studied women were housewives (97.5%).

There was no difference between the groups in the prevalence of side-effects at entry. However, the frequency of nausea, vomiting and constipation were significantly lower in the twice weekly group at both week 24 and week 36 of pregnancy (Table 2). Nevertheless, the occurrence of heartburn did not differ between the 2 groups at the 2 measured intervals.

Table 3 shows the haematological characteristics at delivery of the 2 supplement groups for both maternal and cord blood. There were no differences in initial and delivery Hb and in haematocrit levels between the 2 groups. Moreover, at delivery, the prevalence of maternal anaemia (i.e. Hb < 11 g/dL) was not significantly different between the 2 groups ( $P = 0.21$ ). While ferritin concentrations were significantly lower

in the twice weekly group at delivery ( $P < 0.001$ ), hypoferritinaemia (maternal ferritin < 15 µg/L) was not observed in either group. Ferritin measurement was added to the protocol after the start of the study, so we did not have data for baseline ferritin values for all mothers.

The anthropometric indices of the newborns are presented in Table 4. Although there were no low-birth-weight newborns in the 2 groups, birth weight and length were significantly higher in the daily supplement group ( $P < 0.001$  and  $P < 0.016$  respectively) taking into account that gestational age, sex ratio and maternal weight gain were similar in the 2 groups.

Multiple logistic regression analysis showed that the only factor affecting birth weight was the supplementation method ( $P < 0.001$ ) (Table 5).

Table 1 Characteristics of the studied pregnant women by iron supplementation regimen

Variable	Iron supplementation regimen						P-value
	Total (n = 365)		Daily (n = 173)		Twice weekly (n = 192)		
	No.	%	No.	%	No.	%	
<b>Age (years)</b>							0.96 <sup>a</sup>
< 25	126	34.2	64	37.0	62	31.8	
25–30	157	42.7	73	42.2	84	43.1	
> 30	85	23.1	36	20.8	49	25.1	
<b>Education</b>							0.99 <sup>a</sup>
Primary	88	24.0	41	23.7	47	24.5	
Secondary	262	71.6	124	71.7	137	71.4	
University	16	4.4	8	4.6	8	4.2	
<b>Husband's education</b>							0.98 <sup>a</sup>
Primary	105	28.7	45	26.0	60	30.8	
Secondary	243	65.8	115	66.5	128	65.6	
University	20	5.5	13	7.5	7	3.6	
<b>Job</b>							0.87 <sup>b</sup>
Housewife	357	97.6	169	97.7	190	97.4	
Employed	9	2.4	4	2.3	5	2.6	
<b>Parity</b>							0.41 <sup>b</sup>
0–1	315	86.3	152	87.9	163	83.4	
2–3	50	13.7	21	12.1	29	15.1	
		<b>Mean (SD)</b>		<b>Mean (SD)</b>		<b>Mean (SD)</b>	
<b>BMI (kg/m<sup>2</sup>)</b>		23.4 (1.7)		23.4 (1.8)		23.5 (1.7)	0.58 <sup>c</sup>
<b>Haemoglobin (g/dL)</b>		11.9 (0.7)		11.9 (0.7)		11.9 (0.7)	0.34 <sup>c</sup>

<sup>a</sup>Kolmogorov-Smirnov test; <sup>b</sup>Chi-squared test; <sup>c</sup>Mann-Whitney test.  
SD = standard deviation; BMI = body mass index.

**Table 2 Gastrointestinal side-effects of iron supplementation at different stages of pregnancy by mothers' iron supplementation regimen**

Stage of pregnancy/ symptoms	Iron supplementation regimen		RR (95% CI)
	Daily No. (n = 173)	Twice weekly No. (n = 192)	
<b>Week 24</b>			
Nausea	28	4	7.7 (2.7-21.7)
Vomiting	12	1	13.3 (1.7-101.3)
Constipation	19	9	2.3 (1.1-5.0)
Heartburn	34	39	1.0 (0.6-1.5)
<b>Week 36</b>			
Nausea	19	4	5.2 (1.8-15.1)
Vomiting	8	1	8.8 (1.1-70.2)
Constipation	16	7	2.5 (1.1-6.0)
Heartburn	36	38	1.0 (0.7-1.6)

RR = relative risk; CI = confidence interval.

## Discussion

Twice weekly iron supplementation has been shown to be effective in the prevention of iron deficiency anaemia in non-pregnant women, children and adolescent girls [2,14,15]. The present study results confirmed that it is also useful during pregnancy in low-risk non-anaemic pregnant women and their newborns. Ferritin measurement was added to the protocol after the start of the study, so we had no baseline ferritin values for mothers. However the randomization

process and the observed homogeneity of the baseline characteristics of the 2 groups suggest that initial ferritin values may not have been different between the 2 groups. Hypoferritinaemia, which is presumed to be an indicator for iron deficiency, was not observed in either of the groups. Nevertheless, lower levels of ferritin in mothers supplemented twice weekly may cause postpartum anaemia for them, which we have not investigated. Several studies of anaemic pregnant women also reported comparable increments of Hb comparing the

2 supplementation methods [6,8,10]. Both groups had similar rates of anaemia at delivery, providing evidence that low doses of iron during pregnancy could be beneficial in preventing anaemia. A number of studies showed that reducing the iron dose or intermittent prescriptions are less effective in improving Hb and iron status than a daily standard dose (30-60 mg elemental iron) [1,8,12]. However, this difference was small, with no reported significant effect on pregnancy outcomes and might be related to factors other than type of iron regimen, such as pre-pregnancy haematological status, nutritional behaviour, diet during pregnancy and the prevalence of iron deficiency or other micronutrient deficiencies [16].

Nutritional status was not taken into account in this study, since the population of our sample came from a rather homogenous low socioeconomic status urban population using public health care services. However, pregnancy may change nutritional habits and mothers may be more careful about their nutrition in this period, which could influence the iron stores in the body and consequently affect our results.

The most common micronutrients in addition to iron and folic acid that

**Table 3 Haematological indices of maternal and cord blood by mothers' iron supplementation regimen**

Variable	Iron supplementation regimen				P-value
	Daily		Twice weekly		
	Median	IQR	Median	IQR	
<b>Maternal blood</b>					
Haemoglobin (g/dL)	12.2	1.5	12.1	1.7	0.43
Haematocrit (%)	35.6	3.6	35.8	4.4	0.59
Ferritin (µg/L)	61	44	36	31	< 0.001
<b>Cord blood</b>					
Haemoglobin (g/dL)	14.7	0.9	14.5	1	0.08
Haematocrit (%)	42.9	3.4	42.1	3.6	0.76
Ferritin (µg/L)	102	78	121	88	0.1
<b>Indices</b>					
	No.	%	No.	%	
Maternal anaemia	14	8.3	24	12.3	0.21
Maternal serum ferritin < 45 µg/L	47	35.9	76	52.1	0.007
Cord serum ferritin < 100 µg/L	59	44.0	66	43.7	0.95

IQR = interquartile range.

**Table 4 Anthropometric characteristics of the studied newborns and outcomes in terms of pregnancy weight gain and sex ratio of newborn by mothers' iron supplementation regimen**

Variable	Iron supplementation regimen				P-value <sup>a</sup>
	Daily (n = 168)		Twice weekly (n = 193)		
	Median	IQR	Median	IQR	
<b>Anthropometric characteristics</b>					
Head circumference (cm)	34	1	34	1	0.246
Height (cm)	50	2	50	2	0.018
Weight (g)	3400	237	3300	475	< 0.001
<b>Gestational age (days)</b>	275	11	274	11	0.787
<b>Outcome</b>					
Maternal pregnancy weight gain (kg)	13	3	12	3	0.068
Sex ratio (boy/girl)	1.2		0.9		0.28

<sup>a</sup>Mann-Whitney test.

IQR = interquartile range.

have been studied in Iranian pregnant women are zinc and vitamin A [17]. Very high rates of deficiency were reported for both of these. Since iron supplementation during pregnancy is a part of routine prenatal care, and non-organic iron interferes with zinc absorption, low serum levels of zinc may be expected. However, several studies showed that multiple micronutrient supplementations are not superior to iron or iron and folic acid supplementation in anaemia during pregnancy. Iron consumption was not supervised directly in our study, but we believe that adherence to both protocols was high and can be attributed to appropriate education, reinforcement calls between visits and the special importance given to it during prenatal visits. The fact that compliance with treatment is related to more important factors than gastrointestinal tract side-effects has been reported by other researchers [5,8]. A lower prevalence of gastrointestinal

side-effects were reported by the twice weekly supplemented mothers, which is in line with other studies that reported reducing iron dose or intermittent prescription could decrease these complications [15,18,19]

The relationship of maternal anaemia and cord blood iron status has been established in several studies [20]. In the present study, cord blood Hb and ferritin concentrations were not different between the 2 supplemented groups, while maternal ferritin levels were lower in the twice weekly group, confirming the efficiency of twice weekly iron consumption in preventing fetal anaemia and iron deficiency in the absence of maternal hypoferritinaemia. This is consistent with other studies which showed that even with mild maternal anaemia, the fetal haematological condition remains normal [21]. Higher levels of ferritin in cord blood can be attributed to active transport of iron to the fetus. Nevertheless, several studies have shown

that in severe maternal anaemia these active pathways may fail [22,23].

There were no low-birth-weight infants in either group. The restricted inclusion criteria for the study that recruited only low-risk mothers might be responsible. However, the median birth weight and height in the daily supplemented group were significantly higher than in the twice weekly group, which supports the results of other studies [4,24]. The mechanism of the influence of iron on fetal growth is not well established. It seems that regardless of maternal anaemia, iron supplementation is beneficial to the fetus in terms of anthropometric indices at birth. On the other hand, the increased risk of low birth weight following excess iron consumption is reported by others [25].

Several important issues should be kept in mind concerning anaemia in the Islamic Republic of Iran. Flour fortification with iron and folic acid is a practised nationwide and all products in the country are made with fortified flour. Thus we assumed that exposure to fortified products was the same for participants of both groups. There are many other factors affecting the prevalence of anaemia, in particular, intestinal parasitic infections. In the past, hookworm infections were very common in Mazandaran province (Sari is the capital

**Table 5 Results of linear regression analysis for prediction of newborn birth weight**

Variable	B	SE (B)	$\beta$	P-value
BMI (kg/m <sup>2</sup> )	11.46	8.62	0.069	0.18
Pregnancy weight gain (kg)	-3.59	7.18	0.026	0.61
Gestational age at delivery (days)	1.4	1.79	0.040	0.43
Type of iron supplementation	121.6	29.9	0.210	< 0.001

BMI = body mass index; SE (B) = standard error of B.

city). But based on recent published research, the prevalence of these infections seems to have decreased [26] and they are more common in rural areas and in children. On the other hand, there is evidence in the literature to support the assumption that the most common cause of anaemia in pregnant women is iron-deficiency anaemia. All supplementation programmes are based on this assumption. The results of this study suggest that iron supplementation is not the only solution for combating anaemia in pregnant women.

Our study had several limitations that might affect the comparability of our results. Due to financial issues, blinding was not done, baseline ferritin values were not checked and the number of pills consumed was not supervised directly. On the other hand, the sample size was reasonably large, which makes our comparisons reliable. The results of our study confirm other research showing that current iron supplementation dose is not suitable for all mothers. It seems that in non-anaemic mothers, a smaller dose of iron

is sufficient, and that this might also prevent complications of iron excess. Nonetheless, further studies are needed to suggest any change in current protocol for iron supplementation in Islamic Republic of Iran.

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