Archives of Clinical Trials

Review Article

Effects of Fermix™ Administration on Hematological Parameters and Physical Symptoms Among Patients With Iron Deficiency or Iron Deficiency Anemia: A Retrospective Chart Review

Patrick Choueiry

Medical Director, Surveal Pharma, Beirut, Lebanon

Correspondence

Patrick Choueiry

Medical Director, Surveal Pharma, Beirut, Lebanon

- Received Date: 05 May 2026
- Accepted Date: 30 May 2026
- Publication Date: 05 June 2026

Keywords

Iron deficiency anemia, Iron supplement, Iron Co-supplementation, Hematological parameters, Headache, Muscle cramp, Fatigue.

Abbreviations

CI: Confidence Interval; e-CRF: Electronic Case Report Form; FACIT: Functional Assessment of Chronic Illness Therapy; FRS: Faces Rating Scale; IDA: Iron Deficiency Anemia; MCH: Mean Corpuscular Hemoglobin MCHC: Mean Corpuscular Hemoglobin Concentration; MCV: Mean Corpuscular Volume; NRS: Numerical Assessment Scale; RLS: Restless Legs Syndrome

Abstract

Introduction: *Iron deficiency (ID) and Iron deficiency anemia (IDA) is a common nutritional disorder characterized by low iron levels, resulting in reduced production of healthy red blood cells. While iron supplementation is commonly used in the treatment of IDA, there is limited research on the effects of combined supplementation with other minerals and vitamins.*

Objectives: *This study aims to investigate the effects of a combination of iron, magnesium, folic acid, and vitamins C, D, B6 and B12 on hematological outcomes such as hemoglobin, mean corpuscular volume (MCV), mean corpuscular hemoglobin (MCH), mean corpuscular hemoglobin concentration (MCHC), and ferritin levels as well as on physical symptoms, specifically fatigue and headache in patients diagnosed with ID and IDA. The effect of magnesium in combination on symptoms of magnesium deficiency, such as muscle cramps, was also studied in this specific population.*

Methods: *We reviewed the medical records of 34 patients with ID/IDA at baseline and follow-up after 4 months of Fermix™ supplementation, which is a combination of liposomal iron pyrophosphate, magnesium, folic acid, vitamin D, C, B6, and B12. Hematological parameters and physical symptoms were compared between baseline and follow-up using paired samples t-test and McNemar chi-square test.*

Results: *A total of 34 patients were included. After Fermix™ supplementation, significant improvements were observed in hemoglobin, MCV, MCH, MCHC, and ferritin levels. There was also a significant improvement in the frequency and intensity of headache, fatigue, and muscle cramps.*

Conclusions: *Our results highlight the beneficial effects of iron supplementation combined with magnesium, folic acid, and vitamins C, D, B6, and B12 in improving hematological parameters and alleviating physical symptoms in patients with ID/IDA.*

Introduction

Iron deficiency anemia (IDA) is a global health problem affecting 22.8% of people of all ages [1]. It is a common nutritional disorder characterized by reduced levels of hemoglobin, serum iron and ferritin [2]. Other red blood cell indices are also affected: mean corpuscular volume (MCV), mean corpuscular hemoglobin (MCH), and mean corpuscular hemoglobin concentration (MCHC) are typically low in IDA [3].

Children, pregnant, breastfeeding or menstruating women, people with cancer, and vegans and vegetarians are at high risk of IDA[3]. Common symptoms of IDA usually include extreme weakness and fatigue, headaches and difficulty concentrating. People with IDA also experience shortness of breath and restless legs syndrome (RLS) [4].

Iron supplements are generally prescribed as first-line therapy to replenish iron stores and normalize hemoglobin levels in patients with IDA [5]. Iron salts such as liposomal ferrous pyrophosphate have been shown to be effective in increasing serum hemoglobin and ferritin levels and improving iron deficiency, while being highly bioavailable [6–8].

The management of IDA involves not only iron supplementation, but also focuses on the critical role of other essential vitamins and minerals. It is well established that vitamin C intake significantly enhances the absorption of dietary non-heme iron [9,10]. On the other hand, studies have shown that vitamin D supplementation improves anemia status in critically ill patients due to the potential effect of vitamin D on iron homeostasis and erythropoiesis [11]. An association between magnesium and iron status has also been demonstrated, with magnesium supplementation improving iron parameters even in patients with optimal indices [12].

Citation: Choueiry P. Effects of FermixTM Administration on Hematological Parameters and Physical Symptoms Among Patients With Iron Deficiency or Iron Deficiency Anemia: A Retrospective Chart Review . Arch Clin Trials. 2026;6(2):016.

Treatment with iron and folic acid supplementation was also found to be effective in significantly reducing IDA and improving iron status in women of reproductive age [13]. In addition, a recent study of the effects of iron and vitamin B6 co-supplementation in pregnant women with IDA showed that iron and vitamin B6 significantly increased hemoglobin levels compared with treatment with iron alone [14]. Despite the role of vitamin B12 in normal erythropoiesis, and the fact that combined iron and vitamin B12 deficiencies have been reported [15,16], no studies have been conducted on the potential effects of vitamin B12 supplementation on hematological outcomes and iron status in patients with IDA.

While several studies have evaluated the efficacy of these supplements as monotherapy in the treatment of IDA, studies on the benefits of oral iron supplementation in combination with other minerals and vitamins in the treatment of IDA and its effects on hematological status are still limited. To address this knowledge gap, this study was conducted to evaluate the effects of a combination of iron, folic acid, and vitamins C, D, B6 and B12 supplementation on ferritin levels and other hematological outcomes such as hemoglobin level, MCV, MCH, MCHC, as well as on physical symptoms, specifically fatigue and headache in patients diagnosed with IDA. Another objective was to evaluate the effect of magnesium in combination on symptoms of magnesium deficiency such as muscle cramps in this specific population.

Methods

Study design and settings

This retrospective chart review was conducted in Malta among patients initiated on Fermix™, a combination of liposomal iron pyrophosphate (27mg), magnesium (250mg), folic acid (400µg), vitamin D3 (7.5µg), vitamin C (73µg), vitamin B6 (11 mg), and vitamin B12 (24µg) for the treatment of IDA, between August 2020 and December 2022. Data were extracted from patients' medical records at a baseline time point corresponding to the initial visit and at a follow-up time point 4 months after baseline. Patients for whom complete hematological data were available, along with documented physician assessments of fatigue and other physical symptoms (including headache and muscle cramps), were included in the retrospective chart review.

Data was de-identified on CRF and patients were given numeric codes, to ensure patient confidentiality and privacy. Since the research team had no direct contact with the participants and given the retrospective and observational nature of this low-risk health study, the research team considered that this study did not require approval from an ethics committee.

Study participants

Eligible patients were older than 18 years, whether pregnant or not, with a confirmed diagnosis of IDA based on baseline hemoglobin (≤12 g/dL for women and ≤13 g/dL for men) and/or ferritin (<12 ng/mL) levels.

Patients receiving other iron-containing supplements or multivitamins, those unable to swallow pills, those with an allergy or contraindication to Fermix™ or any of its components, and those who did not provide informed consent were excluded from the study.

Data collection and outcome measures

A case report form (CRF) was developed, and data from two visits (initial visit and 6-month follow-up visit) were transcribed from patient medical records into CRFs by the investigator and then transferred to a central database.

At both the baseline and follow-up visits, data extracted from patients' medical records included patient characteristics such as age, sex, weight, height, occupation, tobacco or alcohol use, pregnancy status, corticosteroid use, chemotherapy status, and adherence to a vegetarian/vegan diet. In addition, at the first visit, data were collected on patients' medical history (cardiovascular disease, cancer, diabetes, kidney disease, hypertension, malabsorption due to inflammatory bowel disease) and the reason for starting Fermix™ supplementation.

The outcome measures of this study extracted from patients' medical records at baseline and follow-up, included hematological parameters, i.e., hemoglobin level, red blood cell indices such as MCV, MCH, and MCHC, and serum ferritin level; symptoms associated with IDA, including self-reported fatigue, and self-reported presence and intensity of headache; and the sign associated with magnesium deficiency, i.e., self-reported presence of muscle cramps.

Fatigue was assessed using the self-reported Functional Assessment of Chronic Illness Therapy (FACIT)-Fatigue scale, which consists of 13 items assessing fatigue, tiredness, weakness, and energy. Item scores can range from 0 ("not at all") to 4 ("very much") and the total score from 0 to 52, with lower scores indicating greater fatigue. The Numerical Rating Scale (NRS) and the Faces Rating Scale (FRS) were used to measure headache intensity, with pain intensity rated from 0 (no pain) to 10 (worst pain).

Statistical methods

Descriptive statistics were performed to summarize baseline patient characteristics using means and standard deviations for continuous variables and frequencies and percentages for categorical variables.

The means of the quantitative variables such as hematological parameters including hemoglobin level, MCV, MCH, MCHC, and serum ferritin, fatigue and headache intensity were compared between baseline and follow-up using paired samples t-test. The percentages of categorical variables such as presence of headache and muscle cramps were compared between baseline and follow-up using McNemar chi-square test.

Results

Patient characteristics

In total, medical records were abstracted at baseline and follow-up for 34 patients who initiated Fermix™ supplementation. Baseline demographic and lifestyle characteristics of the patients are summarized in Table 1. The majority of patients were female (94%), the mean age was 42.0 (standard deviation [SD]=14.0) years, and the mean self-reported weight at the time of Fermix™ initiation was 66.0 (SD=12.2) kg. Only one patient was pregnant, and another was on a vegetarian/vegan diet. While none of the patients reported the use of corticosteroids, chemotherapy, or alcohol, only two patients were identified as smokers.

Hematological parameters

Table 2 summarizes the baseline and follow-up hematological parameters result of all 34 patients. There was a significant overall improvement in hemoglobin level, MCV, MCH, MCHC and serum ferritin level after 4 months of Fermix™ supplementation. Importantly, the observed hemoglobin increase occurred in a population presenting predominantly with mild anemia at baseline.

Table 1. *Sociodemographic and lifestyle characteristics of patients with iron deficiency anemia initiated on Fermix TM included in this study (n=34).*

	Mean	Standard deviation
Age (years)	42.0	14.0
Weight (kg)	66.0	12.2
	Frequency	**Percentage**
Sex *Female* *Male*	32 2	94.1 5.9
Pregnancy	1	2.9
Corticosteroids administration	0	0.0
Chemotherapy initiated	0	0.0
Vegan or vegetarian diet	1	2.9
Tobacco use	2	5.9
Alcohol consumption	0	0.0

Summary statistics are expressed as mean and standard deviation for continuous variables and as frequency and percentage for categorical variables.

Table 2*. Laboratory parameters and physical symptoms of patients with iron deficiency anemia initiated on Fermix TM at baseline and follow-up.*

	Baseline	Follow-up	P-value
Hemoglobin, mean ± SD (g/dL)	11.0 ± 1.6	12.5 ± 1.5	<0.001
MCV, mean ± SD (fL)	81.2 ± 10.8	85.2 ± 10.7	0.014
MCH, mean ± SD (pg)	27.2 ± 3.1	28.6 ± 2.8	0.001
MCHC, mean ± SD (g/dL)	32.0 ± 3.49	33.4 ± 1.5	0.026
Serum ferritin, mean ± SD (ng/mL)	9.9 ± 5.9	16.8 ± 9.9	<0.001
Energy index, mean ± SD	14.8 ± 9.3	9.1 ± 6.4	<0.001
Headache, n/N (%)	21/34 (61.8)	16/34 (47.1)	0.13
Headache intensity, mean ± SD	3.2 ± 2.4	2.2 ± 2.4	0.014
Muscle cramps, n/N (%)	8/34 (23.5)	4/33 (12.1)	0.045

MCV: Mean Corpuscular Volume; MCH: Mean Corpuscular Hemoglobin; MCHC: Mean Corpuscular Hemoglobin Concentration; SD: Standard deviation

Baseline refers to the visit when Fermix TM was initiated, and follow-up refers to the visit after 4 months of Fermix TM supplementation. Summary statistics are expressed as mean and standard deviation for continuous variables and as frequency and percentage for categorical variables.

Symptoms associated with IDA and muscle cramps

As shown in Table 2, there was a significant decrease in the FACIT fatigue scale between baseline (mean [SD] = 14.8 [9.3]) and follow-up (mean [SD] = 9.1 [6.4]). Although many participants reported a decrease in the presence of headache (61.8% at baseline vs. 47.1% at follow-up), that proportion was not statistically significant. Yet, there was a significant decrease in the headache intensity (mean [SD] NRS or FRS = 3.2 [2.4] at baseline vs. 2.2 [2.4] at follow-up). There was also a significant decrease in the proportion of patients reporting the presence of muscle cramps between baseline (23.5%) and after 4 months of Fermix™ supplementation (12.1%). .

Discussion

This retrospective chart review study aimed to evaluate the real-world efficacy of Fermix™, a combination of iron, magnesium, folic acid, and vitamins C, D, B6 and B12, on red blood cell indices, hemoglobin and ferritin levels, symptoms of IDA and magnesium deficiency in a sample of patients with IDA. Our results showed significant increases in hemoglobin, MCV, MCH, MCHC, and serum ferritin levels after 4 months of Fermix™ supplementation. In addition, patients reported a reduction in symptoms such as headache intensity, and the presence of muscle cramps.

Our results regarding the increase in mean hemoglobin and ferritin levels after 4 months of Fermix™ supplementation are consistent with other previous studies and reviews that have examined the role of iron monotherapy in the correction of IDA. These studies reported similar improvements in hemoglobin and ferritin levels in adults, non-pregnant and pregnant women, and children [6,17–20] following iron supplementation for the treatment of IDA. The magnitude of hemoglobin increase observed in this study (+1.5 g/dL after 4 months) should be interpreted considering the relatively mild anemia present at baseline (mean Hb 11.0 g/dL). In populations with mild iron deficiency anemia, smaller absolute increases in hemoglobin are typically observed compared with patients with moderate or severe anemia. Moreover, once hemoglobin approaches the normal range, the rate of increase generally slows and plateaus as erythropoiesis normalizes and iron supplementation contributes primarily to the restoration of iron stores. This is reflected in the concurrent significant increase in ferritin levels observed in the present study. Taken together, these findings suggest that the hematological response observed is consistent with the expected physiological correction of mild iron deficiency anemia.

In our study, the Fermix™ supplement included a relatively new iron compound, liposomal iron pyrophosphate. A recent study found that liposomal iron pyrophosphate supplementation was associated with a significant increase in hemoglobin levels in non-pregnant women with IDA [6]. This highlights the potential role of this specific iron formulation in improving hemoglobin levels in our patients and indicates that the use of an adequate iron supplement is essential to replenish iron stores and correct anemia.

Fermix™ supplementation improved hematological values by increasing MCV, MCH, and MCHC in patients with IDA. This finding is consistent with previous research [21] documenting the positive impact of iron supplementation on red blood cells indices in individuals with IDA, and indicates a positive response to iron supplementation.

However, our study went beyond evaluating the effects of iron alone by examining the potential synergistic effects of other minerals and vitamins including magnesium, folic acid, and vitamins C, D, B6, and B12 which are present in Fermix™. While no studies have specifically examined this combination in IDA and direct comparisons cannot be made, research on the combined use of iron and other single minerals or vitamins has shown improvements in iron status and hematological parameters similar to our findings. In a study of pregnant women with IDA, co-supplementation with iron and vitamin B6 was found to increase hemoglobin levels more than iron alone [14]. Another study in adolescents with IDA found that iron and folic acid co-supplementation increased hemoglobin

levels [22]. However, the addition of vitamin B12 to iron and folic acid supplementation did not improve hemoglobin levels in adolescent girls with anemia [23]. Similarly, the results of a recent clinical trial showed that concurrent vitamin C and iron supplementation wasn't superior to iron monotherapy in improving hemoglobin levels and iron stores in patients with IDA [24].

The analysis revealed a statistically significant reduction in reporting of headaches, fatigue, and muscle cramps after 4 months of Fermix™ supplementation. This finding is consistent with previous studies on the effects of iron supplementation in alleviating headache [25,26], reducing cramps and RLS [25], and reducing fatigue measures [25,27] in iron-deficient patients. It is worth noting that the combination of Fermix™ may have provided additional benefits beyond iron monotherapy, explaining the improvements in symptoms burden in patients with IDA.

Overall, our findings contribute to the existing literature and have implications for improving the management of IDA and the quality of life of affected patients. Further research is required to explore the synergistic effects of this iron-multivitamin combination on hematologic parameters and physical symptoms of IDA.

Strengths and limitations

The present study provides real-world valuable insight into the potential beneficial effects of a combination of iron, magnesium, folic acid, and vitamins C, D, B6, and B12 in the management of IDA. Another notable strength of this study is the use of validated instruments to assess fatigue and headache associated with IDA, which increases the accuracy and consistency of the measurements and strengthens the validity of our results.

However, it is important to note that this study is limited by its retrospective design. Data were collected from patients' medical records without assessing the adherence to the daily supplement dose and without frequent monitoring as in a clinical trial. Other limitations include the relatively small sample of patients, the majority (94%) of whom were female, which limits the generalizability of the results, and the lack of a control group, which makes it difficult to distinguish between the specific effect of FermixTM supplementation and other factors, such as diet or the spontaneous resolution of symptoms associated with IDA during the study period. In addition, the presence of other mineral or vitamin deficiencies in our patients was not evaluated. Undetected concomitant deficiencies may have influenced the response to FermixTM administration and introduced bias into the results by confounding the observed improvements in our study outcomes.

Conclusion

To our knowledge, this is the first study to evaluate the real-world use of FermixTM for the treatment of iron deficiency and IDA. It adds to the body of evidence on the importance of iron supplementation in the management of IDA and highlights the role of iron, and other mineral and vitamin co-supplementation in improving MCV, MCH, MCHC, hemoglobin and ferritin levels, and reducing headaches, fatigue, and cramps in patients with IDA.

Acknowledgments

The participation of the general practitioners in this study has been greatly appreciated. Statistical analysis was conducted by Dr. Kh. Asmar from Research & Evaluation Metrics, Beirut - Lebanon.

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