

Effectiveness of Novel Oral Microencapsulated Ferric Saccharate Strips versus Colloidal Elemental Iron Oral Supplementation in Iron Deficiency Anaemia: An Open-label Randomised Controlled Trial among Children

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ABSTRACT

Introduction: Iron Deficiency Anaemia (IDA) is a major public health problem in children, particularly in low- and middle-income countries. Gastrointestinal intolerance and poor palatability of conventional oral iron often compromise adherence. Microencapsulated ferric saccharate (MFS) oral strips are a novel formulation designed to improve bioavailability and tolerability.

Aim: To compare the effectiveness, tolerability, adverse effects and treatment compliance of MFS oral strips with Colloidal Elemental Iron (CEI) in children aged 4-18 years with IDA.

Materials and Methods: This open-label randomised controlled trial was conducted at KLE Dr. Prabhakar Kore Hospital and Medical Research Centre, KAHER, Jawaharlal Nehru Medical College, Belagavi, Karnataka, India, from September 2024 to October 2025. A total of 60 children aged 4-18 years with IDA were randomised to receive either MFS oral strips or CEI for 12 weeks. Randomisation 1:1 by computer-generated sequence, allocation concealed in sequentially numbered opaque sealed envelopes. Laboratory staff assessing Haemoglobin (Hb) and ferritin were blinded. Deworming with albendazole 400 mg was given to both arms at enrollment before randomisation as per Indian Academy of Paediatrics (IAP) standard care. MFS dose: 27-54 mg/day fixed; CEI dose: 3-6 mg/kg/day (mean 68-139

mg/day based on mean weight 22.8-23.2 kg). Haemoglobin, red cell indices, iron profile, adverse effects and treatment compliance were assessed at baseline and after 12 weeks of therapy. Data were analysed using independent t-test, Chi-square test, Fisher's exact test, Mann-Whitney U test and Wilcoxon signed-rank test. A p-value <0.05 was considered statistically significant.

Results: Sixty children were enrolled, with 30 in each group (MFS=30; CEI=30). Baseline characteristics were comparable, including mean age (8.2±4.1 years vs 8.0±4.3 years) and haemoglobin levels (8.7±0.9 g/dL vs 8.6±0.9 g/dL). At three months, mean Hb rise was significantly higher in the experimental group than the control group (2.7±0.7 g/dL vs 2.0±0.8 g/dL; p-value <0.001). Gastrointestinal adverse effects occurred less frequently with the MFS group, and compliance was significantly better in the intervention group (p-value <0.001).

Conclusion: In this small open-label trial, fixed-dose MFS strips showed greater Hb rise, lower GI events and higher adherence compared with weight-based CEI. This reflects combined effects of tolerability and adherence, not equivalent-dose bioavailability. Larger blinded trials with dose-equivalent comparison and cost-effectiveness are needed.

Keywords: Children, Ferric compounds, Iron strips, Microencapsulation, Oral iron preparations

INTRODUCTION

Anaemia is defined by the World Health Organisation (WHO) as a condition in which the number of red blood cells or their oxygen-carrying capacity is insufficient to meet physiological needs [1]. IDA remains the most prevalent nutritional deficiency globally. The burden is higher in low- and middle-income countries due to poor dietary intake, higher infection rates and limited access to healthcare [2]. According to the WHO, approximately 269 million children worldwide are anaemic, with the highest prevalence (39.8%) observed among children aged 6-59 months globally in 2019 [3]. In India, according to the Comprehensive National Nutrition Survey (CNNS, 2016-18), anaemia affects approximately 40.6% of children aged 1-4 years, 23.5% of children aged 5-9 years, and 28.4% of adolescents aged 10-19 years [4]. Among children under five years specifically, the National Family Health Survey (NFHS) reports a further rise in anaemia prevalence, from 58.4% in NFHS-4 (2015-16) to 67.1%

in NFHS-5 (2019-21) [5]. Among adolescents aged 15-19 years, NFHS-5 (2019-21) reports an anaemia prevalence of 59.1% in girls and 31.1% in boys, reflecting a persistently high burden across the paediatric and adolescent age spectrum in India [5]. In children, IDA is primarily attributed to increased iron requirements during rapid growth, inadequate dietary iron intake, impaired iron absorption, recurrent infections, and poor socio-economic conditions. Iron deficiency adversely affects multiple physiological systems and may lead to significant functional impairments even before the onset of clinically overt anaemia [6]. Beyond impaired haemoglobin synthesis, iron deficiency has been associated with delayed cognitive and psychomotor development, impaired learning ability, behavioural disturbances, reduced physical performance, diminished immune function, and poor growth [7].

Oral iron supplementation is the recommended first-line therapy for uncomplicated paediatric IDA because of its effectiveness, safety,

and low cost [6,8]. Conventional oral iron preparations such as ferrous sulphate, ferrous fumarate, ferrous ascorbate, and colloidal elemental iron are widely used in clinical practice [9,10]. However, gastrointestinal adverse effects including nausea, vomiting, abdominal pain, constipation, diarrhoea, metallic taste, and dental staining frequently reduce treatment adherence, often resulting in incomplete therapy and suboptimal haematological recovery [9,10].

Recent advances in oral iron delivery have led to the development of MFS, in which ferric iron is encapsulated within a calcium-alginate matrix that facilitates pH-dependent intestinal release, minimises gastric irritation, and enhances bioavailability [11-13]. Clinical studies have shown iron absorption comparable to ferrous sulphate with improved gastrointestinal tolerability [11,12]. A preclinical study has demonstrated that microencapsulation improves iron bioavailability and accelerates recovery from IDA compared with conventional non-encapsulated iron formulations [14]. The oral strip formulation offers additional advantages including ease of administration, absence of metallic taste, prevention of dental staining, and potential improvement in compliance, critical determinants of successful paediatric iron therapy [12]. Given the high burden of childhood IDA in India and the limitations of conventional oral iron preparations, this study was conducted to compare the efficacy, tolerability, and adverse effect profile of MFS oral strips with CEI in children aged 4-18 years with IDA. This trial compares two clinically relevant regimens in practice, not equivalent elemental iron doses.

MATERIALS AND METHODS

A randomised controlled trial was conducted at KLE Dr. Prabhakar Kore Hospital and Medical Research Centre, KAHER, Jawaharlal Nehru Medical College, Belagavi, Karnataka, India, from September 2024 to October 2025. The study was approved by the Institutional Ethics Committee, JNMC, Belagavi (IEC No: MDC/JNMCIEC/223) and registered prospectively with the Clinical Trials Registry-India (CTRI/2024/06/068424). The study was conducted in accordance with the Declaration of Helsinki (1975, revised 2013). Written informed consent was obtained from parents/guardians prior to enrollment of children aged 4-18 years. In addition, oral assent was obtained from children aged 7-11 years and written assent from those aged 12-18 years. Children aged 4-18 years attending the inpatient and outpatient services and diagnosed with IDA were screened for eligibility.

Inclusion criteria: Children aged 4-18 years with IDA, defined according to WHO haemoglobin cut-offs (Hb <11 g/dL for 6 months-5 years, <11.5 g/dL for 5-12 years, and <12 g/dL for 12-18 years) [1]. Along with biochemical evidence of iron deficiency (low serum ferritin and/or serum iron with elevated TIBC), attending out/in-patient at the Department of Paediatrics during the study period were included in the study.

Exclusion criteria: Children with recent blood transfusion, prior iron therapy, hypersensitivity to study medications, severe anaemia requiring parenteral iron, or associated chronic systemic illness were excluded from the study.

Sample size calculation: $n = 2\sigma^2(Z\alpha/2 + Z\beta)^2/d^2$.

Based on Ganguly S et al., who assumed an expected between-group Hb-rise difference of 2 g/dL with a common standard deviation of 2 g/dL in a comparable paediatric trial of ferrous ascorbate versus colloidal iron, a minimum of 23 children per group was required at 90% power and a two-sided α of 0.05 [10]. A total of 30 children per group ($n = 60$) were enrolled. Participants were randomised in a 1:1 ratio using a computer-generated random sequence prepared by an investigator not involved in recruitment. Allocation concealment was ensured using sequentially numbered opaque sealed envelopes. Owing to differences in formulation (oral strip versus syrup), blinding of participants and investigators was not feasible; therefore, the study was conducted as an open-label RCT. All participants underwent deworming with albendazole

(400 mg, single dose) at enrollment as part of standard care, prior to randomisation and initiation of iron therapy, to minimise the confounding effect of helminthic infestation on haematological response. Based on the prescribed dosing regimens, the mean elemental iron dose received was 27-54 mg/day in the MFS group (fixed-dose strips). In the CEI group, based on weight-based dosing (3-6 mg/kg/day) and the mean body weight of 22.8-23.2 kg, the estimated mean elemental iron dose ranged from approximately 68 to 139 mg/day. Group A received MFS oral strips (1-2 strips/day; 27 mg elemental iron/strip; maximum 54 mg/day), administered according to the recommended therapeutic regimen, whose bioavailability is similar to that of conventional ferrous salts [11,12]. Group B received CEI syrup at 3-6 mg/kg/day of elemental iron in one or two divided doses, for 12 weeks [15]. As duodenal iron absorption saturates at approximately 25 mg per dose, with minimal proportional increase beyond this threshold [16,17], MFS was formulated as a fixed 27 mg/strip dose rather than a weight-based regimen. All study medications were provided free of cost, and no charges were incurred by the parents or guardians. Baseline demographic, anthropometric, Haematological, and iron profile parameters were recorded. Follow-up assessments after three months included haemogram, iron profile, adverse events, and treatment compliance. The primary outcome measure was the mean increase in Hb at three months. Secondary outcomes included anaemia correction, changes in iron profile and red cell indices, adverse events, and treatment adherence. Compliance was assessed by caregiver-reported adherence and residual drug count at follow-up visits. Treatment compliance was calculated as: Compliance (%) = (Dose consumed ÷ Dose prescribed) × 100. Compliance in the MFS group was assessed by counting unused strips, whereas in the CEI group it was determined by measuring the residual syrup volume returned at each follow-up visit. Sixty children with IDA who met the eligibility criteria were enrolled and randomised equally into the MFS group ($n=30$) and the CEI group ($n=30$). All randomised participants were followed-up for 12 weeks and included in the final analysis on an intention-to-treat basis [Table/Fig-1]; one participant in the MFS group and four in the CEI group discontinued the study medication during the trial but continued to be assessed at scheduled follow-up visits.

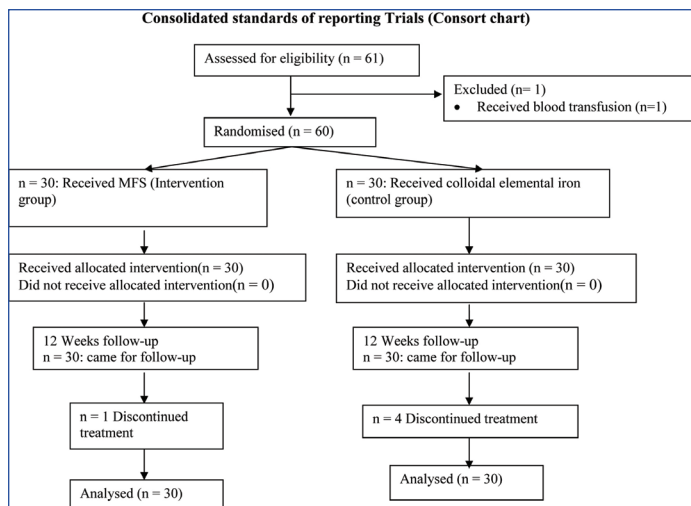
STATISTICAL ANALYSIS

Data were analysed using Statistical Package for the Social Sciences (SPSS) software version 27.0. Continuous variables were expressed as mean±SD or median (IQR), and categorical variables as frequencies and percentages. Normality was assessed using the Shapiro-Wilk test. Independent and paired t-tests were used for normally distributed continuous variables, while the Mann-Whitney U test and Wilcoxon signed-rank test were used for non-parametric data. Categorical variables were compared using Fisher's exact test. A p-value <0.05 was considered statistically significant.

RESULTS

Baseline socio-demographic, anthropometric, haematological, and iron profile parameters - including age, sex distribution, Hb, red cell indices Mean Corpuscular Volume (MCV), Mean Corpuscular Haemoglobin (MCH), Red Cell Distribution Width (RDW), and iron profile parameters serum ferritin, serum iron, Total Iron Binding Capacity (TIBC), and Transferrin Saturation (TSAT) - were comparable between the two groups. Age, sex, and weight were not significant [Table/Fig-2].

At 12 weeks, the MFS group demonstrated significantly greater improvement in iron profile parameters, with significantly higher serum ferritin (p-value <0.001), serum iron (p-value=0.02), and TSAT (p-value=0.02) compared with the CEI group; TIBC did not differ significantly between groups (p-value=0.112) [Table/Fig-3]. Gastrointestinal adverse effects were less frequent with MFS than with CEI (16.7% vs 43.3%, p-value=0.024) [Table/Fig-4], while



[Table/Fig-1]: Screening, randomisation and inclusion of study participants in the analysis.

Variable	Experimental group (n = 30)	Control group (n = 30)	Test	Statistic	p-value
Age (years), mean±SD	8.2±4.1	8.0±4.3	t-test	t=0.18	0.854
Age category 4-18 y			Chi-square	χ ² =0.159	0.924
Age category 4-<9 y	15 (50.0)	15 (50.0)			1.00
Age category 9-<14 y	10 (33.3)	11 (36.7)			0.787
Age category 14-18 y	5 (16.7)	4 (13.3)			0.718
Sex category			Chi-square	χ ² =0.067	0.796
Male	16 (53.3)	15 (50.0)			0.80
Female	14 (46.7)	15 (50.0)			0.80
Weight (kg), mean±SD	23.2±9.0	22.8±9.2	t-test	t=0.17 df=58	0.87

[Table/Fig-2]: Comparison of baseline demographic and anthropometric variables between experimental group and control group in the present study.

Values are expressed as mean±SD or n (%). Independent samples t-test used for continuous variables (Age, Weight); Chi-square test used for categorical variables (Age category, Sex), with Fisher's-exact test applied where expected cell count was <5. p<0.05 was considered statistically significant

Parameters	Experimental group (n=30)	Control group (n=30)	Group A 12 Weeks	Group B 12 Weeks	Statistic	p-value (12w)
Haemoglobin (g/dL), mean±SD	8.7±0.93	8.6±0.91	11.4±0.8	10.6±0.9	t=3.65	<0.001*
MCV (fL), mean±SD	68.2±6.4	67.8±6.8	75.3±3.4	72.2±3.2	t=3.25	0.002*
MCH (pg), mean±SD	21.0±2.1	20.8±2.0	23.9±1.3	22.6±1.2	t=3.45	0.001*
RDW (%), mean±SD	17.7±2.0	17.5±1.9	15.5±1.1	16.2±1.0	t=3.38	0.0125*
Serum ferritin (ng/mL), median (IQR)	9.0 (7.2-11.0)	9.0 (6-11.8)	26 (20-33)	18.0 (13-25)	U=264 Z=2.75	0.0001*
Serum iron (µg/dL), mean±SD	35.2±11.5	34.6±11.2	71.4±18.5	60.2±19.0	t=2.31	0.02*
TIBC (µg/dL), mean±SD	408±55	412±58	352±46	372±50	t=-1.61	0.112
TSAT (%), mean±SD	8.6±3.1	8.4±3.0	20.4±6.5	16.3±6.4	t=2.46	0.02*

[Table/Fig-3]: Comparison of haematological and iron profile parameters at baseline and at 12weeks between experimental group and control group in the present study. Independent samples t-test; Mann-Whitney U test used for Serum ferritin p<0.05 was considered statistically significant.

Side effects	Experimental group (n=30)	Control group (n=30)	Odds ratio	Fisher's-exact test	p-value
Nausea	1 (3.3)	5 (16.7)	0.17	0.194	0.19
Vomiting	1 (3.3)	4 (13.3)	0.22	0.353	0.35
Abdominal pain	2 (6.7)	8 (26.7)	0.20	0.080	0.08
Constipation	1 (3.3)	7 (23.3)	0.11	0.052	0.05
Diarrhea	0	4 (13.3)	0.00	0.112	0.11
Any GI adverse effect*	5 (16.7)	13 (43.3)	-	-	0.024

[Table/Fig-4]: Comparison of specific adverse effects between experimental group and control group in the present study.

Fisher's-exact test, p<0.05 was considered statistically significant

*number of children with at least one GI symptom in each group

mean treatment compliance was significantly higher in the MFS group (94.0±7.0% vs 83.0±15.0%; p-value <0.001).

DISCUSSION

In the present randomised trial, both groups were well matched at baseline for Hb and ferritin levels. Over 12 weeks, children receiving MFS demonstrated a significantly greater rise in Hb and superior ferritin recovery compared with those receiving CEI. Despite this significant Hb correction, ferritin levels at 12 weeks remained below the normal reference range in both groups, reflecting incomplete repletion of iron stores. This is a well-recognised pattern in IDA treatment, as Hb normalisation typically precedes full store repletion; current recommendations advise continuing iron therapy for 2-3 months after Hb correction. The 12-week endpoint likely captured the haematological response before complete ferritin normalisation, which may require a longer treatment or follow-up duration [18]. Gastrointestinal adverse effects were considerably more frequent in the CEI group and compliance was correspondingly higher with MFS, reflecting the combined effect of better tolerability and palatability that likely contributed to its superior therapeutic outcomes. It is important to note that the two arms received different dosing strategies: fixed-dose MFS (27-54 mg/day) vs weight-based CEI (3-6 mg/kg/day). As intestinal iron absorption saturates at ~25 mg per dose [16,17,19], the fixed-dose strip was used within the effective absorptive range to improve practicality for children. Thus, this trial compares the effectiveness of two regimens, not equivalent elemental iron doses. The superior haematological response with MFS therefore reflects the combined effect of formulation, tolerability, and adherence, rather than bioavailability alone.

Conventionally, the recommended dose of elemental iron for the treatment of IDA in children is 3-6 mg/kg/day [15,20]; however, lower doses (approximately 3 mg/kg/day) have been shown to be equally effective and better tolerated, and are therefore currently recommended [9,10,16,17,20].

Contreras C et al., conducted a randomised, double-blind, crossover study at the Department of Health Sciences, Universidad Católica San Antonio de Murcia (UCAM), Murcia, Spain, in 17 healthy adults (11 men, 6 women) aged 18-35 years to compare the oral

absorption of MFS with Ferrous Sulphate (FS). A dose of 39±3.8 mg elemental iron was administered once daily on Day 1 and Day 8, with blood samples drawn six hours after each dose. Transferrin saturation increased significantly following intake of both products (p-value <0.005), with no significant difference between MFS and FS, indicating that iron absorption from MFS was equivalent to that of FS. However, as this study was conducted in healthy, non-iron-deficient adults using a single-dose design, these findings cannot be directly extrapolated to iron-deficient children [11].

Lazaro E et al., in a rat model of IDA, found that both ferrous sulfate (FeSO₄) and MFS (AB-Fortis®; 10 mg iron/kg diet) produced significant improvements in body weight, reticulocyte count, and haemoglobin content of reticulocytes versus untreated controls

(p-value <0.01), with no significant difference between the two iron forms (12.7±0.2 pg vs 12.5±0.3 pg; p-value >0.05). As this was an animal model, extrapolation to paediatric IDA should be made cautiously [14].

Zeckanovic A et al., conducted a randomised, placebo-controlled trial between December 2017 and June 2020 across 15 paediatric primary care centres in Slovenia, evaluating microencapsulated ferric iron syrup dosed at 1 mg/kg/day of elemental iron in 94 children aged 9 months to six years. After 12 weeks, the intervention group demonstrated higher haemoglobin (122.0±8.5 vs 117.0±8.3 g/L; p-value=0.02) and ferritin levels (24.5±12.3 vs 19.6±7.9 µg/L; p-value=0.04) compared with placebo, with good compliance and a favorable safety profile, supporting the improved haematological response and tolerability observed with MFS in the present study [13].

Friling M et al., conducted a randomised, double-blind crossover trial in 51 healthy premenopausal women receiving MFS (n=26) or FS (n=25) at a matched dose of 60 mg/day of elemental iron. Oral MFS was associated with significantly improved tolerability compared to conventional FS, with fewer gastrointestinal complaints (nausea, abdominal pain, flatulence, diarrhoea) and reduced frequency, intensity, and duration of symptoms overall [12]. It should also be noted that this study was conducted in healthy adult women, and its tolerability findings may not directly generalise to iron-deficient children.

Powers JM et al., conducted a randomised clinical trial at a tertiary paediatric centre in the United States between September 2013 and November 2015, involving 80 children aged 9-48 months with nutritional IDA. The study compared low-dose FS with iron polysaccharide complex, each given at 3 mg/kg/day of elemental iron for 12 weeks. Children receiving FS demonstrated a significantly greater increase in Hb concentration (7.9 to 11.9 g/dL vs 7.7 to 11.1 g/dL), a higher rate of complete resolution of IDA (29% vs 6%), and a greater increase in serum ferritin (15.6 vs 7.5 ng/mL) [20].

Yewale VN and Dewan B conducted a study at a tertiary care paediatric centre in Navi Mumbai in 2013 among 73 children aged six months to 12 years, comparing ferrous ascorbate and colloidal iron (3 mg/kg/day elemental iron). At 12 weeks, mean Hb rise was significantly higher with ferrous ascorbate (3.59±1.67 g/dL) than colloidal iron (2.43±1.73 g/dL), with greater anaemia correction (64.9% vs 31.0%; p-value <0.01) [9]. Similarly, Ganguly S et al., study at NRS medical college, Kolkata, India between January 2009 and February 2010 among 80 children aged six months to 12 years demonstrated superior haematological response with ferrous ascorbate, showing a mean Hb increase of 3.24±1.66 g/dL versus 1.42±2.04 g/dL with colloidal iron after 12 weeks (both groups received 3 mg/kg/day of elemental iron), along with significantly higher responder rates (53.6% vs 10.3%; p-value <0.01) [10].

Limitation(s)

The study was limited by its single-centre setting, relatively small sample size, short follow-up duration, and open-label design, which may affect generalisability; the investigational product was administered as a fixed-dose oral strip, whereas the comparator was dosed according to body weight. Therefore, the study evaluated the comparative effectiveness of two clinically relevant treatment regimens rather than equivalent weight-based elemental iron doses.

CONCLUSION(S)

The MFS oral strips demonstrated superior efficacy, better tolerability, and improved adherence compared to CEI supplementation in children with IDA. This reflects combined effects of tolerability and adherence, not equivalent-dose bioavailability. Future studies incorporating formal cost-effectiveness analysis would help establish the economic value of this formulation in paediatric anaemia management.

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- Plagiarism X-checker: May 14, 2026
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- Was informed consent obtained from the subjects involved in the study? Yes
- For any images presented appropriate consent has been obtained from the subjects. NA

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