

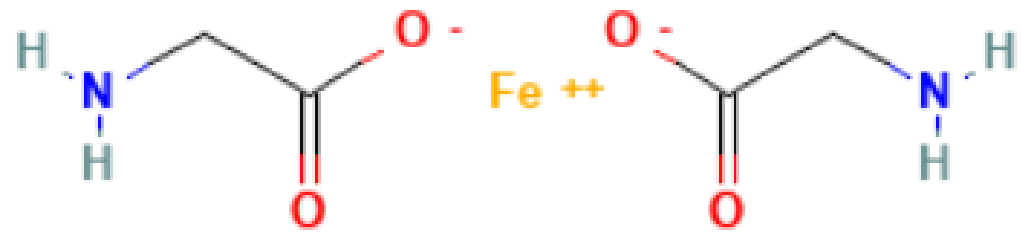
Ferrous bisglycinate chelate

Introduction

- ▶ Ferrous bisglycinate chelate (FeBC) is a highly stable compound composed of 2 glycine molecules bound to a ferrous cation by covalent and coordinate covalent bonds
- ▶ FeBC exhibits greater tolerability and lower incidence of adverse effects compared to iron salts, such as Ferrous Sulphate or Ferrous Fumarate, which represent important advantages of FeBC for treating iron deficiency anaemia.
- ▶ Ferrous bisglycinate is an amino acid iron chelate that has at least 2-fold higher bioavailability than conventional iron salts, such as Ferrous sulphate or Ferrous Fumarate, and has been associated with fewer adverse GI side effects.
- ▶ Because of the superior bioavailability, smaller doses of ferrous bisglycinate is warranted as compared to conventional iron salts.
- ▶ Unlike other iron salts, FeBC absorption is proportional to iron demand, showing it to be a safe compound for treating IDA.
- ▶ FeBC is efficacious in treating IDA in special populations, such as in children and pregnant women.

Ferrous bisglycinate: Chemical Structure

- ▶ Ferrous bisglycinate is a chelate that is used as a source of dietary iron. Forming a ring structure when reacting with glycine, ferrous bisglycinate acts as both a chelate and a nutritionally functional. It is found in foods for food enrichment or in supplements for the treatment of iron deficiency or iron deficiency anemia.

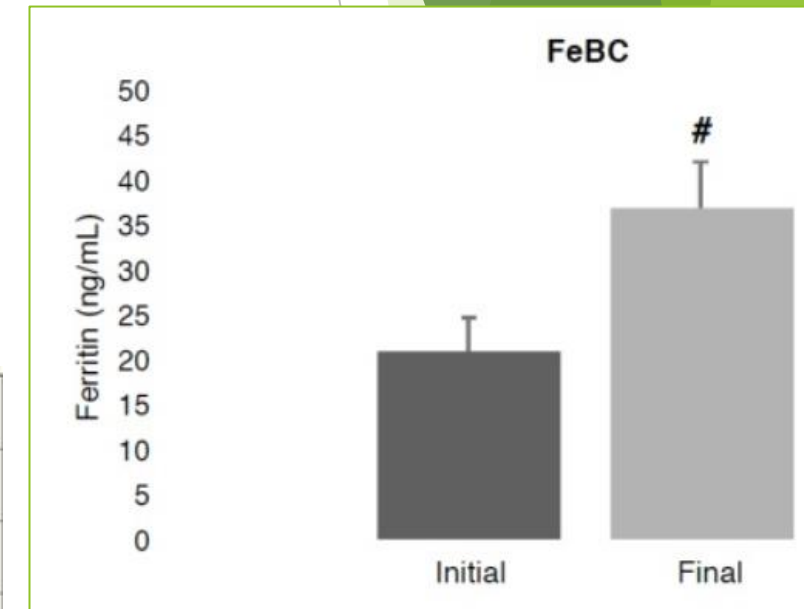


FeBC efficacy in special population group: in Children

► Children diagnosed with IDA were supplemented with iron bisglycinate chelate. The effects of FeBC treatment for 45 days on haemoglobin, Mean Corpuscular Volume (MCV), Mean Corpuscular Hemoglobin (MCH), Cell Distribution Width (RDW), transferrin, and ferritin levels are shown below.

Group	FeBC
Type of treatment	Iron bisglycinate chelate
Number of participants	9
Age (years)	3.9±1.2
Gender (Males)	6
Body weight (kg)	16.1±1.8

Parameter	FeBC		
	Initial	Final	95% CI
Hemoglobin (g/dL)	10.7±0.2	12.2±0.3*	[0.925; 2.053]
MCV (fL)	72.5±2.4	74.2±2.3*	[0.290; 2.933]
MCH (pg)	24.4±1.0	24.9±0.9*	[0.038; 0.940]
RDW (%)	14.4±0.5	15.0±0.4*	[0.061; 0.961]
Ferritin (ng/mL)	21±3.9	37±5.0*	[9.337; 22.219]



FeBC versus Ferrous Fumarate efficacy in special population group: in Pregnant women

► Iron deficiency in pregnancy is a major public health problem that causes maternal complications. The bioavailability, efficacy, and safety of oral ferrous bisglycinate supplementation was examined in pregnant women with iron deficiency. Women were randomly allocated to receive oral iron as ferrous bisglycinate (equiv. iron 24 mg) or as ferrous fumarate (equiv. iron 66 mg iron) after breakfast daily. FeBC was found comparable to standard ferrous fumarate for the clinical management of iron deficiency during pregnancy, while FeBC had comparatively better absorption, tolerability, and efficacy and with a lower elemental iron dosage.

Iron Status	Baseline			3 Months after Supplementation			6 Months after Supplementation		
	Ferrous Bisglycinate Plus Folinic Acid	Control	P	Ferrous Bisglycinate Plus Folinic Acid	Control	P	Ferrous Bisglycinate Plus Folinic Acid	Control	P
Hb (g/dL)	10.04 ± 0.83	10.17 ± 0.77	0.415	12.40 ± 0.68	11.78 ± 0.72	<0.001	12.82 ± 0.66	12.09 ± 0.60	<0.001
Mean Change				2.356 ± 0.69	1.61 ± 0.838	<0.001	2.78 ± 0.822	1.92 ± 0.89	<0.001
Erythrocytes (×10 ¹² /L)	2.23 ± 0.42	2.11 ± 0.30	0.066	3.93 ± 0.437	3.23 ± 0.36	<0.001	4.22 ± 0.30	3.41 ± 0.317	<0.001
Mean Change				1.69 ± 0.581	1.12 ± 0.33	<0.001	1.98 ± 0.49	1.30 ± 0.35	<0.001
Reticulocytes (×10 ⁹ /L)	45.98 ± 4.53	43.15 ± 4.15	0.051	63.71 ± 6.69	55.77 ± 3.88	<0.001	69.91 ± 6.32	57.70 ± 4.48	<0.001
Mean Change				17.73 ± 7.99	12.62 ± 4.03	<0.001	23.93 ± 8.12	14.55 ± 5.02	<0.001

Ferrous bisglycinate	120 mg	Ferrous fumarate	200 mg
Equiv. iron	24 mg	Equiv. iron	66 mg
Folic acid (vitamin B9)	400 mcg	Folic acid (vitamin B9)	400 mcg
Ascorbic acid (vitamin C)	50 mg	Ascorbic acid (vitamin C)	50 mg
Thiamine nitrate (vitamin B1)	5 mg	Thiamine nitrate (vitamin B1)	5 mg
Riboflavine (vitamin B2)	5 mg	Riboflavine (vitamin B2)	5 mg
Pyridoxine (vitamin B6)	5 mg	Pyridoxine (vitamin B6)	5 mg
Cyanocobalamin (vitamin B12)	10 mcg	Cyanocobalamin (vitamin B12)	10 mcg

Comparison of birth-weight between ferrous bisglycinate plus folinic acid and control groups.

	Iron Supplementation		P
	Ferrous Bisglycinate Plus Folinic Acid	Control	
Newborn weight (g)	3103.82 ± 270.85	2992.26 ± 254.86	0.029

FeBC versus Ferrous Sulphate and ferrous glycine sulfate efficacy in special population group: in Pregnant women

- ▶ Studies have compared the effects of oral ferrous bisglycinate 25 mg iron/day vs. ferrous sulphate 50 mg iron/day in the prevention of iron deficiency (ID) and iron deficiency anemia (IDA) in pregnant women. Ferrous bisglycinate in a low dose of 25 mg iron/day appears to be equivalent to double dose of ferrous sulphate (50mg) in preventing IDA in more effective way during pregnancy and postpartum. Newborns weight was slightly higher in the bisglycinate vs. the sulphate group (3601 ± 517 g vs. 3395 ± 426 g, $P=0.09$).
- ▶ Studies have compared the efficacy and tolerability of oral ferrous bis-glycinate versus ferrous glycine sulphate in the treatment of iron deficiency anaemia (IDA) with pregnancy. The mean increase in HB level after 8 weeks of treatment in ferrous bis-glycinate group was 2.48 ± 0.12 g/dL versus 1.32 ± 0.18 g/dL in ferrous glycine sulfate group ($p \leq .0001$). The percentage of women with HB level more than 11 g/dL after 8 weeks of treatment was 89.2% in ferrous bis-glycinate group versus 71.3% in ferrous glycine sulfate group ($p < .0001$). The rate of adverse effects was significantly higher in ferrous glycine sulfate group ($p = .001$). Thus, it has been inferred that Pregnant women with second trimester IDA could be supplied with ferrous bis-glycinate which is more efficient in increasing HB level. Moreover, it has tolerable adverse effects and high compliance than ferrous glycine sulphate.



**FERROUS
SULPAHTE**

FeBC efficacy in other vulnerable patient population

- ▶ **Chronic kidney disease and hemodialysis patients:** Fixed-dose ferrous bisglycinate chelate supplements are well tolerated in CKD and HD patients. The supplement combination is able to improve iron status in NDD CKD patients and compensate for the potential iron loss in HD patients. Oral ferrous bisglycinate chelate might be an alternative for parenteral iron supplementation in CKD stage 3b to 4 and HD patients.
- ▶ **Mild non-chemotherapy-induced iron deficiency anemia in cancer patients:** In cancer patients mild-moderate non-chemotherapy-induced iron deficiency anemia (IDA) is usually treated with oral iron salts, mostly ferrous sulphate. However, ferrous bisglycinate chelate has similar efficacy and lower GI toxicity than ferrous sulphate given at the conventional dosage.
- ▶ **Preterm infants:** Supplementation with iron bisglycinate chelate at a dose of 0.75 mg/kg/day demonstrated an efficacy comparable to iron sulphate at a dose of 3 mg/kg/day in preterm infants. The higher bioavailability of iron bisglycinate chelate resulted in a lower load of elemental iron, a quarter of the dose, and achieved equivalent efficacy compared to iron sulphate. Iron bisglycinate chelate thus should be used in the prevention and treatment of preterm newborn anaemia.
- ▶ **Preoperative Anaemia in Orthopaedic Surgical Patients:** Oral iron support with FeBC in patients undergoing preoperative autologous blood donation (PABD) programs has been suggested by different authors to improve red blood cell (RBC) production and limit iron depletion. Oral administration of low doses of ferrous bisglycinate chelate is an effective and safe therapy to support PABD and to treat iron deficiency before surgery.

