

Larinject

Ferric Carboxymaltose Injection 50 mg/ml (10 ml Vial)

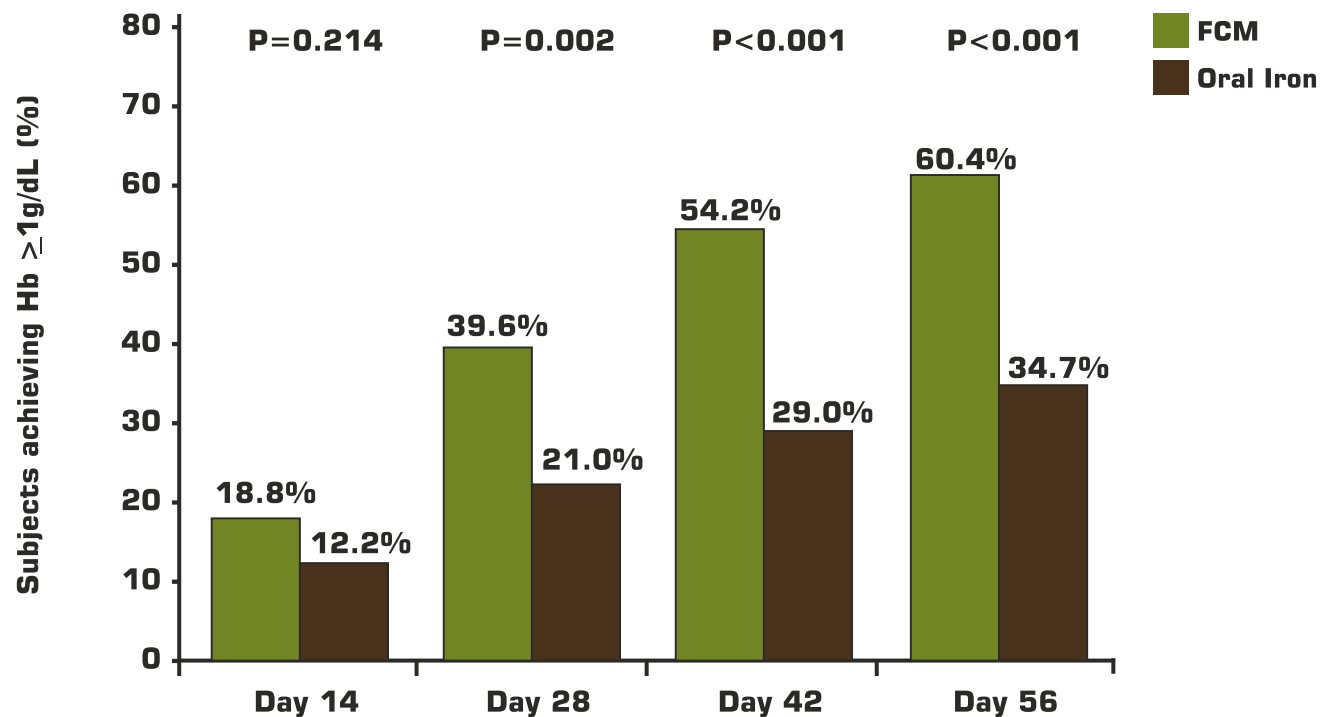
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Clinical Evidences

1. Ferric Carboxymaltose (FCM) vs Oral Iron for treatment of Iron deficiency anaemia in NDD-CKD Patients

- An open-label trial on 255 CKD patients (GFR \leq 45 mL/min/1.73 m²)
- **Duration:** 56 days
- **Two Groups:** (1) FCM Group: (n=147) (2) Oral Iron Group (n=103)
- **Outcomes:**



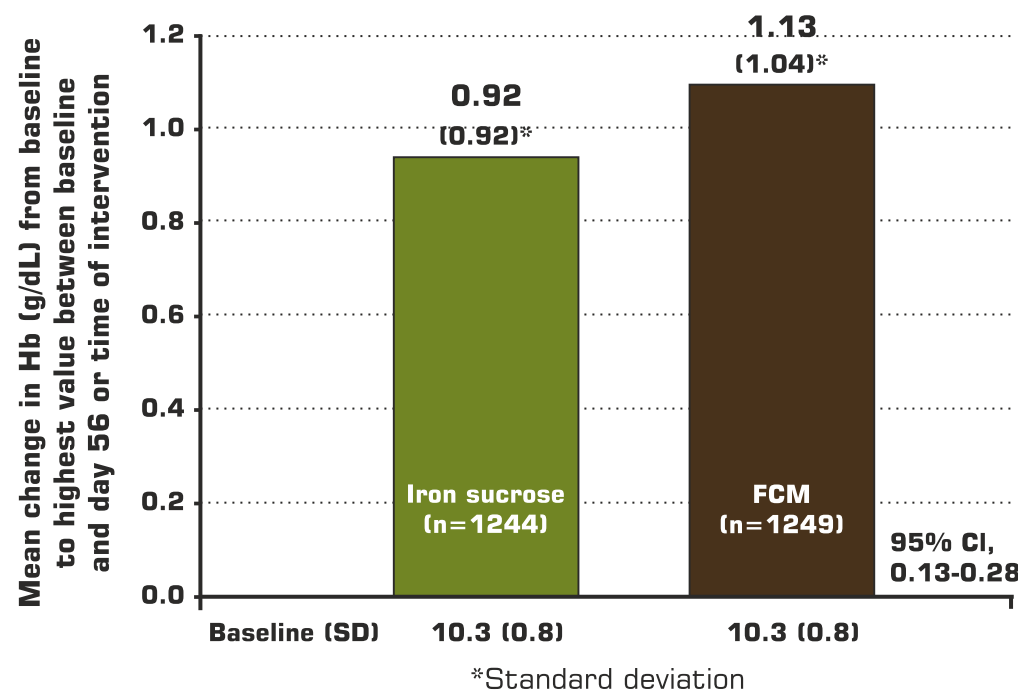
Parameters	FCM	Oral Iron
Proportion of subjects achieving a Hb increase \geq 1 g/dL (%)	60.4%	34.7%
Mean increase in hemoglobin (g/dL)	0.95 \pm 1.12	0.50 \pm 1.23
Mean increase in Ferritin (ng/ml)	432 \pm 189	18 \pm 45
Mean increase in TSAT (%)	13.6 \pm 11.9	6.1 \pm 8.1

Ferric carboxymaltose is more effective and is better tolerated than oral iron for treatment of iron deficiency in ND-CKD patients.

Reference: Nephrol. Dial Transplant. 2011 May; 26(5):1599-607

2. Ferric Carboxymaltose (FCM) vs Iron Sucrose in NDD-CKD Patient

- A Randomized, active-controlled, multicenter, noninferiority, open-label Trial
- Duration: 56 Days
- **Two Groups:** (1) FCM Group: (n= 1276) (2) Iron Sucrose Group (n= 1285)



Mean change in Hb level from baseline to highest value was greater with FCM than iron sucrose

Reference: Nephrol Dial Transplant. 2014 Apr;29(4):833-42

3. Ferric Carboxymaltose Safely Improves Hemoglobin in Dialysis Patients

- The study enrolled 163 HD patients who received 200 mg of iron as FCM via IV bolus push injection into the dialysis venous line two to three times weekly for up to 6 weeks.

Parameters	Baseline	After 6 weeks
Mean hemoglobin levels (g/dL)	9.1	10.3
Mean ferritin (µg/L)	67.3	333.6
TSAT (%)	17.4	31

FCM is well-tolerated and effective in the correction of Hb levels and iron stores in patients with IDA undergoing HD.

Reference: Nephrol Dial Transplant. 2010 Aug; 25(8): 2722-2730

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Description:

- Larinject is an intravenous iron preparation, a medicine that is used in the treatment of iron deficiency conditions.
- It contains iron in the form of ferric carboxymaltose, an iron carbohydrate compound. Iron is an essential element required for the oxygen-carrying capacity of hemoglobin in red blood cells and of myoglobin in muscle tissue.

Indication:

- Larinject (ferric carboxymaltose injection) is an iron replacement product indicated for the treatment of iron deficiency anemia (IDA) in adult patients
- Who have intolerance to oral iron or who have had unsatisfactory response to oral iron or
- Who have non-dialysis-dependent chronic kidney disease (NDD-CKD) and dialysis dependent CKD

Dosage & Administration:

- Larinject must only be administered by the intravenous route: by injection, by infusion, or during a Haemodialysis session undiluted directly into the venous limb of the dialyser.
- Intravenous injection: Larinject may be administered by intravenous injection using undiluted solution up to a maximum single dose of 1,000 mg iron (up to a maximum of 15 mg iron/kg body weight).
- Intravenous infusion: Larinject may be administered by intravenous infusion up to a maximum single dose of 1,000 mg iron (up to a maximum of 20 mg iron/kg body weight).

Hb (g/dl)	Patients with body weight ≥35 kg and < 70 kg	Patients with body weight ≥70 kg
< 10	1500 mg	2000 mg
≥ 10	1000 mg	1500 mg

Ferric carboxymaltose	Iron	Maximum amount of sterile 0.9% NaCl solution	Minimum administration time
2 to 4 ml	100 to 200 mg	50 ml	-
>4 to 10 ml	>200 to 500 mg	100 ml	6 minutes
> 10 to 20 ml	>500 to 1000 mg	250 ml	15 minutes

Hemodialysis-dependent chronic kidney disease

In hemodialysis-dependent chronic kidney disease patients, a single daily injection of LARINJECT should not exceed 200 mg iron.

*Please refer pack insert for further clarity on Dosage and Administration

Presentation:

- Larinject is available as a Vial of 10 ml. Each 10 mL vial contains 500 mg of iron as ferric carboxymaltose.

La Renon

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