Cresp®
Darbepoetin alfa 25/40/60µg

Dr.Reddy's

Darbepoetin Alfa Stays Akin to Erythropoietin Alfa for Anemia in Nephrology

Does darbepoetin alfa, at a reduced dose frequency, stands to be non-inferior to erythropoietin alfa in efficacy, tolerability, and safety for renal anemia in CKD?

Mehta *et al.* compared the efficacy and tolerability of DA-α to EPO in the treatment of renal anemia among Indian pre-dialysis patients with CKD in a non-inferiority trial.

Study design

Phase III, randomized, open-label, parallel-group, multicenter, active-controlled, non-inferiority trial from September 2012 to May 2014 at 14 sites across India

Study population

63 patients aged 18–65 years at pre-dialysis stage 3 and 4 with GFR 15-59 mL/min/1.73 m^2 and Hb 7–10 g/dL, EPO naïve or on EPO (not within 1 week prior to screening)

Intervention

Patients with Hb <10 g/dL received EPO TIW or DA-α QW (1:1) for 12–24 weeks (correction phase) in ITT and PP groups. Patients with Hb 10 g/dL were switched to DA-α or EPO for 12 weeks (maintenance phase).

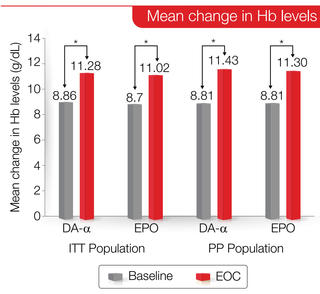
Endpoints

- **Efficacy:** Mean change in Hb level from baseline to EOC
- **Safety**

Darbepoetin alfa stands to be non-inferior to EPO in efficacy and safety measures for renal anemia in pre-dialysis CKD patients.

Efficacy: Comparative mean change in Hb levels

Mean change in Hb levels from baseline to EOC.

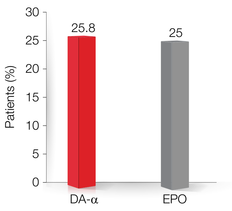


Difference in the mean Hb change of DA-α and EPO groups was **not statistically significant.**

*p<0.001

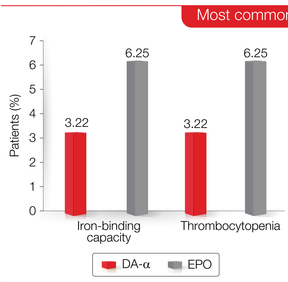
Safety: Frequency and types of TEAEs

Patients experiencing at least one TEAE.



Similar proportion of patients experienced at least 1 TEAE in DA-α and EPO groups.

Most commonly reported TEAEs.



Similar proportion of patients experienced the most common TEAEs in DA-α and EPO groups.

No changes in mean blood pressure or heart rate.

No patient in DA-α but 1 in EPO group experienced study drug-related TEAE.

No unexpected changes in hematology, biochemistry, and coagulation findings

No antibody formation to either treatment

For renal anemia in pre-dialysis CKD patients, DA-α at a reduced dose frequency is as effective and well tolerated as EPO.

Change for Better...Change to

Cresp®
Darbepoetin alfa 25/40/60µg

Abbreviations: CKD: Chronic kidney disease; DA-α: Darbepoetin alfa; EOC: End of correction phase; EPO: Erythropoietin alfa; GFR: Glomerular filtration rate; Hb: Hemoglobin; ITT: Intent to treat; PP: Per protocol; QW: Once weekly; TEAE: Treatment emergent adverse events; TIW: Three times a week.

Reference: Mehta KS, Sinha SD, Vamsi B, *et al.* Darbepoetin alfa versus erythropoietin alfa for treatment of renal anemia in patients with chronic kidney disease at the pre-dialysis stage: A randomized non-inferiority trial. *J Assoc Physicians India.* 2019;67(1):62–66.