



# Prairie

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## EDUCATION & RESEARCH COOPERATIVE

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### RED HF

- Trial Sponsor:** Amgen
- Principal Investigator:** Stephen Jennison, MD / Nasar Nallamothu, MD
- Trial Name:** A Double-Blind, Randomized, Placebo-Controlled, Multicenter Study to Assess the Efficacy and Safety of Darbepoetin Alfa Treatment on Mortality and Morbidity in Heart Failure (HF) Subjects With Symptomatic Left Ventricular Systolic Dysfunction and Anemia
- Purpose:** The purpose of the study is to determine the efficacy of treatment of anemia with darbepoetin alfa compared to placebo on the composite of time to death from any cause or first hospital admission for worsening HF in subjects with symptomatic left ventricular systolic dysfunction and anemia.
- Details:** Several epidemiological studies have demonstrated an association between HF and anemia and correlation of increased risk for mortality and hospitalization with low hemoglobin in patients with HF. Earlier single-center interventional studies suggest that meaningful clinical benefits may be achieved by raising hemoglobin concentration in patients with symptomatic HF and anemia. Data from Amgen's completed phase 2 multi-center studies support this hypothesis and show that darbepoetin alfa is well tolerated in patients with symptomatic left ventricular systolic dysfunction and anemia and effectively raises hemoglobin. The pivotal phase 3 Study 20050222 RED-HF Trial is evaluating the effect of treatment with darbepoetin alfa on the composite risk of all-cause mortality or hospitalization for worsening HF in subjects with symptomatic left ventricular systolic dysfunction and anemia. This study also evaluates the effect of darbepoetin alfa treatment on all-cause death, on cardiovascular death or hospitalization for worsening HF, and on patient-reported quality-of-life outcomes.



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### **Eligibility**

**Ages Eligible for Study:** 18 years and above

**Genders Eligible for Study:** Both

**Inclusion Criteria:**

- HF of at least 3 months duration and of NYHA class II, III, or IV
- hemoglobin between 9.0 g/dL and 12.0 g/dL
- left ventricular ejection fraction equal to or less than 40%

**Exclusion Criteria:**

- Transferrin saturation (Tsat) < 15%
- Blood pressure > 160/100 mm Hg
- Heart failure primarily due to valvular heart disease or clinically significant valvular heart disease that might lead to surgical correction within 12 months of randomization
- Recipient of a major organ transplant or receiving renal replacement therapy
- Serum creatinine > 3.0 mg/dL (> 265 µmol/L)