ForPatients
by Roche

Neurodegenerative Disorder

A Study of Epoetin Beta Treatment in Anemic Participants With Myelodysplastic Syndrome (MDS)

Trial Status	Trial Runs In	Trial Identifier
Completed	1 Country	NCT02145026 ML29005

The information is taken directly from public registry websites such as ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com, etc., and has not been edited.

Official Title:

A Prospective Open-Label Study of the Effectiveness of Epoetin Beta for Treating Anemic Patients With Low/Intermediate-1-Risk Myelodysplastic Syndrome (MDS)

Trial Summary:

This is a Phase IV, prospective, multi-center, open-label study to assess the effectiveness and safety profile of epoetin beta (Recormon®) for treatment of symptomatic anemia in adult participants associated with low/intermediate-1-risk MDS. After screening, eligible participants will be treated with epoetin beta as recommended in the approved label and international guidelines for the use of epoetin in MDS participants and the dosage will be adjusted on the basis of erythroid response.

Hoffmann-La Roche
Sponsor

Phase 4
Phase

NCT02145026 ML29005
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	# 18 Years	No

Inclusion Criteria:

- Adult participants with low or intermediate-1 risk MDS
- No previous treatment with hematopoietic growth factors within 3 months prior to screening
- Symptomatic anemia (hemoglobin <10 g/dL) as determined by investigator

- Serum erythropoietin <500 milliunits/milliliter (mU/mL) within 14 days prior to the first dose of study treatment
- Require no red blood cell transfusion or dependent on <4 units within 8 weeks prior to screening
- Clinically stable for at least 1 month prior to entry into the study
- For female participants of childbearing potential and male participants with partners of childbearing potential, agreement (by participants and/or partner) to use highly effective form(s) of contraception

Exclusion Criteria:

- Contraindications and/or known hypersensitivity to the active substance and/or any of the excipients of epoetin beta treatment
- Poorly controlled hypertension as assessed by the investigator
- History of Acute Myeloid Leukemia (AML) or high risk for AML
- Administration of another investigational drug within 1 month before screening or planned during the study period
- Previously documented evidence of Pure Red Cell Aplasia (PRCA)