ForPatients
by Roche

Renal AnemiaRenal FailureChronic Kidney Disease

Ascertain the Optimal Starting Dose of Mircera Given Subcutaneously for Maintenance Treatment of Anemia in Pediatric Patients With Chronic Kidney Disease on Dialysis or Not Yet on Dialysis.

Trial Status	Trial Runs In	Trial Identifier
Completed	7 Countries	NCT03552393 2016-004779-39 NH19708

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:

An Open-Label, Single-Arm, Multicenter Study to Ascertain the Optimal Starting Dose of MIRCERA® Given Subcutaneously for the Maintenance Treatment of Anemia in Pediatric Patients With Chronic Kidney Disease on Dialysis or Not Yet on Dialysis.

Trial Summary:

Ascertain the starting dose of Mircera given subcutaneously for the maintenance treatment of anemia in pediatric participants with chronic kidney disease (CKD) on dialysis or not yet on dialysis when switching from stable subcutaneous (SC) maintenance treatment with epoetin alfa, epoetin beta, or darbepoetin alfa.

Hoffmann-La Roche	Phase 2
Sponsor	Phase

NCT03552393 2016-004779-39 NH19708
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	# 3 Months & # 17 Years	No

Inclusion Criteria:

- Pediatric participants 3 months to 17 years of age with clinically stable chronic renal anemia

- CKD with estimated glomerular filtration rate (eGFR) of < 45 mL/min/1.73 m2 (determined by the Bedside Schwartz formula) or dialysis treatment for at least 8 weeks before the first dose of Mircera
- For participants on peritoneal dialysis (PD): a weekly Kt/V# 1.8
- For participants on hemodialysis (HD): adequate HD, urea reduction ratio (URR) > 65% or Kt/V > 1.2 for participants on HD three times per week.

Participants with fewer than or more than three HD sessions per week should have a weekly Kt/V# 3.6.

- Baseline Hb concentration 10.0-12.0 g/dL determined from the mean of two Hb values measured at Visit 1 (Week -3) and Visit 2 (Week -1)
- Stable SC maintenance treatment with epoetin alfa, epoetin beta, or darbepoetin alfa with the same dosing interval for at least 6 weeks before the first dose of Mircera
- Stable dose of epoetin alfa, epoetin beta, or darbepoetin alfa treatment with no weekly dose change > 25% (increase or decrease) for at least 4 weeks before the first dose of Mircera
- Adequate iron status defined as ferritin#100 ng/mL or transferrin saturation (TSAT)# 20% (or percentage of hypochromic red cells < 10%); mean of two values measured during screening.

Exclusion Criteria:

- Overt gastrointestinal bleeding within 8 weeks before screening or during the screening period
- RBC transfusions within 8 weeks before screening or during the screening period
- Hemoglobinopathies (e.g., homozygous sickle-cell disease, thalassemia of all types) Hemolytic anemia, Active malignant disease
- PD subjects with an episode of peritonitis within the past 30 days prior to screening and/or during the screening period
- Uncontrolled or symptomatic inflammatory disease (e.g., systemic lupus erythematosus)
- Uncontrolled hypertension as assessed by the investigator
- Epileptic seizures within 3 months prior to screening and during the screening period
- Administration of any investigational drug within 4 weeks prior to screening or planned during the study
- Severe hyperparathyroidism (intact parathyroid hormone [PTH]# 1000 pg/mL or whole PTH# 500 pg/mL) or biopsy-proven bone marrow fibrosis
- Kidney transplant with use of immunosuppressive therapies known to exacerbate anemia
- Known hypersensitivity to recombinant human erythropoietin (EPO), polyethylene glycol, or any constituent of the study drug formulation
- Anti-EPO antibody (AEAB)-mediated pure red cell aplasia (PRCA) or history of AEAB mediated PRCA or positive AEAB test result in the absence of PRCA
- High likelihood of early withdrawal or interruption of the study (e.g., planned living donor kidney transplant within 5 months of study start)
- Planned elective surgery during the entire study period