ForPatients
by Roche

Chronic Kidney Disease

A Study to Assess All-Cause Mortality and Cardiovascular Morbidity in Participants With Chronic Kidney Disease (CKD) on Dialysis and Those Not on Renal Replacement Therapy Receiving Methoxy Polyethylene Glycol-Epoetin Beta (Mircera) or Reference Erythropoietin Stimulating Agents (ESAs)

Trial Status	Trial Runs In	Trial Identifier
Completed	27 Countries	NCT00773513 2007-005129-31 BH21260

The source of the below information is the publicly available website ClinicalTrials.gov. It has been summarised and edited into simpler language.

Trial Summary:

This 2 arm safety study will compare the outcome with respect to a composite endpoint of all-cause mortality and non-fatal cardiovascular events (myocardial infarction, stroke) in CKD participants either on dialysis or not receiving renal replacement therapy under treatment with methoxy polyethylene glycol-epoetin beta or reference ESAs. Participants will be randomized to receive intravenous (iv) or subcutaneous (sc) methoxy polyethylene glycol-epoetin beta at the following doses: for participants not already receiving ESA treatment, methoxy polyethylene glycol-epoetin beta will be administered at a starting dose of 0.6 micrograms per kilograms every 2 weeks (mcg/kg/2wks) iv or sc; for participants receiving maintenance ESA treatment, iv or sc methoxy polyethylene glycol-epoetin beta will be administered at an initial monthly dose of 120, 200 or 360 micrograms (mcg) depending on the weekly dose of ESA received prior to first methoxy polyethylene glycol-epoetin beta administration. Participants randomized to reference ESA treatment will receive iv or sc ESAs in accordance with their prescribed dosing information.

Hoffmann-La Roche	Phase 4
Sponsor	Phase

NCT00773513 2007-005129-31 BH21260
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	>=18 Years	No