ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
Release Date: September 16, 2016

ClinicalTrials.gov ID: NCT00642304

Study Identification

Unique Protocol ID:	ML20937
Brief Title:	A Study of Subcutaneous C.E.R.A. for the Maintenance of Hemoglobin Levels in Participants With Chronic Renal Anemia Not on Dialysis.
Official Title:	A Single Arm Open Label Study to Assess Efficacy, Safety and Tolerability of Once-monthly Administration of Subcutaneously C.E.R.A. for the Maintenance of Hemoglobin Levels in Patients With Chronic Renal Anemia Not on Dialysis
Secondary IDs:	

Study Status

Record Verification:	September 2016
Overall Status:	Completed
Study Start:	July 2008
Primary Completion:	December 2009 [Actual]
Study Completion:	January 2010 [Actual]

Sponsor/Collaborators

Sponsor:	Hoffmann-La Roche
Responsible Party:	Sponsor
Collaborators:	

Oversight

FDA Regulated?:	No

IND/IDE Protocol?:	No
Review Board:	Approval Status: Approved Approval Number: M07-026 Board Name: Medisch Ethische Toetsingscommissie Noord-Holland Board Affiliation: Medisch Centrum Alkmaar Phone: 0031 72 548 23 15 Email: metc.nh@mca.nl
Data Monitoring?:	
Plan to Share IPD?:	
Oversight Authorities:	Netherlands:Medicines Evaluation Board

Study Description

Brief Summary:	This single arm study will assess the efficacy and safety of subcutaneous C.E.R.A. when administered for the maintenance of hemoglobin levels in participants with chronic renal anemia, not on dialysis. Participants currently receiving maintenance treatment with subcutaneous darbepoetin alfa or epoetin beta will receive monthly injections of C.E.R.A., with the starting dose (120, 200 or 300 micrograms [mcg] subcutaneously [SC]) derived from the dose of darbepoetin alfa or epoetin beta they were receiving in the week preceding study start.
Detailed Description:	

Conditions

Conditions:	Anemia
Keywords:	

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 3
Intervention Model:	Single Group Assignment
Number of Arms:	1
Masking:	Open Label
Allocation:	N/A
Endpoint Classification:	Safety/Efficacy Study

Enrollment: 20 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: methoxy polyethylene glycol-epoetin beta	Drug: methoxy polyethylene glycol-epoetin beta [C.E.R.A.] Methoxy polyethylene glycol-epoetin beta is administered SC every four week up to Week 20.The starting dose is 120, 200 or 300 mcg based on the dose of darbepoetin alfa or epoetin beta participants shall be receiving in the week preceding the study start. Further dose adjustment during the study depending on the hemoglobin (Hb) values.

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age: 18 Years

Maximum Age:

Gender: Both

Accepts Healthy Volunteers?: No

Criteria: Inclusion Criteria:

- Chronic renal anemia
- Stable darbepoetin alfa or epoetin beta therapy for past 8 weeks

Exclusion Criteria:

- Transfusion of red blood cells during previous 8 weeks
- Poorly controlled hypertension requiring interruption of epoetin treatment in previous 6 months
- Acute or chronic bleeding requiring therapy within previous 8 weeks

Contacts/Locations

Study Officials: Clinical Trials
Study Director
Hoffmann-La Roche

Locations: Netherlands

Goes, Netherlands, 4462 RA

Almelo, Netherlands, 7609 PP

Doetinchem, Netherlands, 7009 BL

Amsterdam, Netherlands, 1034 CS

Delft, Netherlands, 2625 AD

Dordrecht, Netherlands, 3318 AT

Nijmegen, Netherlands, 6525 GA

Leiden, Netherlands, 2333 ZA

Amersfoort, Netherlands, 3818 ES

Utrecht, Netherlands, 3582 KE

References

Citations:

Links:

Study Data/Documents:

Study Results

Participant Flow

Reporting Groups

	Description
Methoxy Polyethylene Glycol-epoetin Beta	Methoxy polyethylene glycol-epoetin beta was administered subcutaneously (SC) every four weeks up to Week 20. The starting dose was 120, 200 or 300 micrograms (mcg) based on the dose of darbepoetin alfa or epoetin beta they were receiving in the week preceding the study start. Further dose was adjusted during the study depending on the hemoglobin (Hb) levels.

Overall Study

	Methoxy Polyethylene Glycol-epoetin Beta
Started	20
Completed	14
Not Completed	6
Adverse Event	1
Death	1
Blood transfusion	2
Erythropoiesis Stimulating Agent Use.	1
Transplantation	1

Baseline Characteristics

Baseline Analysis Population Description

Safety population included all participants who received at least one dose trial medication and underwent a safety follow-up, whether withdrawn prematurely or not.

Reporting Groups

	Description
Methoxy Polyethylene Glycol-epoetin Beta	Methoxy polyethylene glycol-epoetin beta was administered SC every four weeks up to Week 20. The starting dose was 120, 200 or 300 mcg based on the dose of darbepoetin alfa or epoetin beta they were receiving in the week preceding the study start. Further dose was adjusted during the study depending on the Hb levels.

Baseline Measures

		Methoxy Polyethylene Glycol-epoetin Beta
Overall Number of Participants		20
Age, Continuous Mean (Standard Deviation) Unit of measure: years	Number Analyzed	20 participants
		64.5 (16.83)

		Methoxy Polyethylene Glycol-epoetin Beta
Gender, Male/ Female Measure Type: Count of Participants Unit of measure: participants	Number Analyzed	20 participants
	Female	5 25%
	Male	15 75%

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Percentage of Participants Maintaining Hb Concentration Within +/-1 Gram Per Deciliter (g/dL) of Their Reference Hb and Between 10.5 to 12.5 g/dL Throughout the Efficacy Evaluation Period (EEP)
Measure Description	The reference Hb value was taken as the time adjusted average of all Hb assessments during the Stability Verification Period (SVP) (Week -4 to Week 0). EEP was from Week 16 to Week 24.
Time Frame	EEP (Weeks 16 to 24)
Safety Issue?	No

Analysis Population Description

The Intent- to -treat (ITT) population included all participants who received at least one dose of trial medication at Week 0 and for whom data for at least one follow-up variable (adverse event) was available.

Reporting Groups

	Description
Methoxy Polyethylene Glycol-epoetin Beta	Methoxy polyethylene glycol-epoetin beta was administered SC every four weeks up to Week 20. The starting dose was 120, 200 or 300 mcg based on the dose of darbepoetin alfa or epoetin beta they were receiving in the week preceding the study start. Further dose was adjusted during the study depending on the Hb levels.

Measured Values

	Methoxy Polyethylene Glycol-epoetin Beta
Number of Participants Analyzed	20
Percentage of Participants Maintaining Hb Concentration Within +/-1 Gram Per Deciliter (g/dL) of Their Reference Hb and Between 10.5 to 12.5 g/dL Throughout the Efficacy Evaluation Period (EEP) Number (95% Confidence Interval) Unit of measure: Percentage of participants	40 (19.1 to 64.0)

2. Secondary Outcome Measure:

Measure Title	Mean Change in Hb Concentration Between SVP and the EEP
Measure Description	The mean change in the time-adjusted average Hb concentration between the two study periods SVP (Baseline) and EEP is presented. The SVP was defined as Week -4 to Week 0. The EEP was defined as Week 16 to Week 24.
Time Frame	SVP (Week -4 to Week 0) and EEP (Week 16 to Week 24)
Safety Issue?	No

Analysis Population Description

ITT population

Reporting Groups

	Description
Methoxy Polyethylene Glycol-epoetin Beta	Methoxy polyethylene glycol-epoetin beta was administered SC every four weeks up to Week 20. The starting dose was 120, 200 or 300 mcg based on the dose of darbepoetin alfa or epoetin beta they were receiving in the week preceding the study start. Further dose was adjusted during the study depending on the Hb levels.

Measured Values

	Methoxy Polyethylene Glycol-epoetin Beta
Number of Participants Analyzed	20
Mean Change in Hb Concentration Between SVP and the EEP Mean (Standard Deviation) Unit of measure: g/dL	0.2 (1.15)

3. Secondary Outcome Measure:

Measure Title	Percentage of Participants Maintaining Hb Concentration Within Hb Range 10.5 to 12.5 g/dL During the EEP
Measure Description	The EEP was defined as Week 16 to Week 24.
Time Frame	EEP (Weeks 16 to 24)
Safety Issue?	No

Analysis Population Description

ITT population

Reporting Groups

	Description
Methoxy Polyethylene Glycol-epoetin Beta	Methoxy polyethylene glycol-epoetin beta was administered SC every four weeks up to Week 20. The starting dose was 120, 200 or 300 mcg based on the dose of darbepoetin alfa or epoetin beta they were receiving in the week preceding the study start. Further dose was adjusted during the study depending on the Hb levels.

Measured Values

	Methoxy Polyethylene Glycol-epoetin Beta
Number of Participants Analyzed	20
Percentage of Participants Maintaining Hb Concentration Within Hb Range 10.5 to 12.5 g/dL During the EEP Number (95% Confidence Interval) Unit of measure: Percentage of participants	50.0 (27.2 to 72.8)

4. Secondary Outcome Measure:

Measure Title	Mean Time Spent in Hb Range of 10.5 to 12.5 g/dL During the EEP
Measure Description	The EEP was defined as Week 16 to Week 24.
Time Frame	EEP (Weeks 16 to 24)
Safety Issue?	No

Analysis Population Description
ITT population

Reporting Groups

	Description
Methoxy Polyethylene Glycol-epoetin Beta	Methoxy polyethylene glycol-epoetin beta was administered SC every four weeks up to Week 20. The starting dose was 120, 200 or 300 mcg based on the dose of darbepoetin alfa or epoetin beta they were receiving in the week preceding the study start. Further dose was adjusted during the study depending on the Hb levels.

Measured Values

	Methoxy Polyethylene Glycol-epoetin Beta
Number of Participants Analyzed	20

	Methoxy Polyethylene Glycol-epoetin Beta
Mean Time Spent in Hb Range of 10.5 to 12.5 g/dL During the EEP Mean (Standard Deviation) Unit of measure: Days	36.5 (24.4)

5. Secondary Outcome Measure:

Measure Title	Percentage of Participants With Blood Transfusion
Measure Description	
Time Frame	Baseline up to Week 28
Safety Issue?	No

Analysis Population Description
ITT population

Reporting Groups

	Description
Methoxy Polyethylene Glycol-epoetin Beta	Methoxy polyethylene glycol-epoetin beta was administered SC every four weeks up to Week 20. The starting dose was 120, 200 or 300 mcg based on the dose of darbepoetin alfa or epoetin beta they were receiving in the week preceding the study start. Further dose was adjusted during the study depending on the Hb levels.

Measured Values

	Methoxy Polyethylene Glycol-epoetin Beta
Number of Participants Analyzed	20
Percentage of Participants With Blood Transfusion Measure Type: Number Unit of measure: Percentage of participants	10

6. Secondary Outcome Measure:

Measure Title	Percentage of Participants With Dose Adjustment
Measure Description	A dose adjustment was defined as a change versus the preceding dose. It included dose increase and dose reduction from the dose given at Baseline.

Time Frame	Baseline up to Week 20
Safety Issue?	No

Analysis Population Description
ITT population

Reporting Groups

	Description
Methoxy Polyethylene Glycol-epoetin Beta	Methoxy polyethylene glycol-epoetin beta was administered SC every four weeks up to Week 20. The starting dose was 120, 200 or 300 mcg based on the dose of darbepoetin alfa or epoetin beta they were receiving in the week preceding the study start. Further dose was adjusted during the study depending on the Hb levels.

Measured Values

	Methoxy Polyethylene Glycol-epoetin Beta
Number of Participants Analyzed	20
Percentage of Participants With Dose Adjustment Measure Type: Number Unit of measure: Percentage of participants	60

Reported Adverse Events

Time Frame	Baseline up to Week 28
Additional Description	[Not specified]

Reporting Groups

	Description
Methoxy Polyethylene Glycol-epoetin Beta	Methoxy polyethylene glycol-epoetin beta was administered SC every four weeks up to Week 20. The starting dose was 120, 200 or 300 mcg based on the dose of darbepoetin alfa or epoetin beta they were receiving in the week preceding the study start. Further dose was adjusted during the study depending on the Hb levels.

Serious Adverse Events

	Methoxy Polyethylene Glycol-epoetin Beta
	Affected/At Risk (%)
Total	6/20 (30%)
Cardiac disorders	
Myocardial infarction [A] *	1/20 (5%)
Gastrointestinal disorders	
Diverticular perforation [A] *	1/20 (5%)
Infections and infestations	
Pneumonia [A] *	2/20 (10%)
Investigations	
Blood Potassium increased [A] *	1/20 (5%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
Breast cancer [A] *	1/20 (5%)
Renal and urinary disorders	
Renal failure chronic [A] *	1/20 (5%)
Respiratory, thoracic and mediastinal disorders	
Dyspnoea [A] *	1/20 (5%)
Surgical and medical procedures	
Haemodialysis [A] *	1/20 (5%)
Renal transplant [A] *	1/20 (5%)

* Indicates events were collected by non-systematic methods.

A Term from vocabulary, MedDRA (12.0)

Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 5%

	Methoxy Polyethylene Glycol-epoetin Beta
	Affected/At Risk (%)
Total	17/20 (85%)
Blood and lymphatic system disorders	
Anaemia [A] *	1/20 (5%)
Cardiac disorders	
Atrial Fibrillation [A] *	1/20 (5%)
Gastrointestinal disorders	
Constipation [A] *	1/20 (5%)
Dyspepsia [A] *	1/20 (5%)
Regurgitation [A] *	1/20 (5%)
General disorders	
Hypothermia [A] *	1/20 (5%)
Infections and infestations	
Bronchitis [A] *	1/20 (5%)
Cystitis [A] *	2/20 (10%)
Erysipelas [A] *	1/20 (5%)
Fungal infection [A] *	1/20 (5%)
Fungal skin infection [A] *	1/20 (5%)
Herpes zoster [A] *	1/20 (5%)
Urinary tract infection [A] *	1/20 (5%)
Investigations	
Blood calcium increased [A] *	1/20 (5%)
Blood phosphorus increased [A] *	2/20 (10%)

	Methoxy Polyethylene Glycol-epoetin Beta
	Affected/At Risk (%)
Blood potassium increased [A] *	2/20 (10%)
Blood pressure increased [A] *	1/20 (5%)
Metabolism and nutrition disorders	
Dehydration [A] *	1/20 (5%)
Gout [A] *	1/20 (5%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
Keratoacanthoma [A] *	1/20 (5%)
Nervous system disorders	
Headache [A] *	1/20 (5%)
Speech disorder [A] *	1/20 (5%)
Transient ischaemic attack [A] *	1/20 (5%)
Renal and urinary disorders	
Renal failure chronic [A] *	2/20 (10%)
Urinary bladder haemorrhage [A] *	1/20 (5%)
Respiratory, thoracic and mediastinal disorders	
Asthma [A] *	1/20 (5%)
Skin and subcutaneous tissue disorders	
Dermatosis [A] *	1/20 (5%)
Skin ulcer [A] *	1/20 (5%)
Vascular disorders	
Haematoma [A] *	1/20 (5%)
Hypertension [A] *	7/20 (35%)

* Indicates events were collected by non-systematic methods.

A Term from vocabulary, MedDRA (12.0)

Limitations and Caveats

[Not specified]

More Information

Certain Agreements:

Principal Investigators are NOT employed by the organization sponsoring the study.

There IS an agreement between the Principal Investigator and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

The Study being conducted under this Agreement is part of the Overall Study. Investigator is free to publish in reputable journals or to present at professional conferences the results of the Study, but only after the first publication or presentation that involves the Overall Study. The Sponsor may request that Confidential Information be deleted and/or the publication be postponed in order to protect the Sponsor's intellectual property rights.

Results Point of Contact:

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