ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
Release Date: 06/09/2016

ClinicalTrials.gov ID: NCT00642668

Study Identification

Unique Protocol ID:	ML21348
Brief Title:	A Study of Subcutaneous Mircera for the Maintenance Treatment of Participants With Chronic Renal Anemia
Official Title:	Subcutaneous Treatment of Anemia in Patients With a GFR Below 45 ml/Min/1.73m2 Through Injections With Mircera as Low Frequent as Once Monthly (STABILO)
Secondary IDs:	

Study Status

Record Verification:	June 2016
Overall Status:	Completed
Study Start:	June 2008
Primary Completion:	December 2009 [Actual]
Study Completion:	December 2009 [Actual]

Sponsor/Collaborators

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

Oversight

FDA Regulated?:	Yes
Applicable Trial?:	Section 801 Clinical Trial? No

	Delayed Posting? No
IND/IDE Protocol?:	No
Review Board:	Approval Status: Approved Approval Number: 7/49/280 Board Name: Comite Voor Medische Ethiek Board Affiliation: Universitair Ziekenhuis Antwerpen Phone: 03 821 35 44 Email: ethisch.comite@uza.be
Data Monitoring?:	
Plan to Share Data?:	
Oversight Authorities:	Belgium: Federal Agency for Medicines and Health Products, FAMHP

Study Description

Brief Summary:	This single arm study assessed the efficacy and safety of subcutaneous methoxy polyethylene glycol-epoetin beta (Mircera), a continuous erythropoietin receptor activator (C.E.R.A.), for correction and/or maintenance of hemoglobin levels in participants with chronic kidney disease and renal anemia, who were not treated with erythropoiesis-stimulating agents (ESA) or on dialysis. Eligible participants received monthly subcutaneous injections of methoxy polyethylene glycol-epoetin beta at an initial recommended dose of 1.2 micrograms/kilogram (mcg/kg). The anticipated time on study treatment was 3-10 months, and the target sample size was 200 individuals.
Detailed Description:	

Conditions

Conditions:	Anemia
Keywords:	

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 4
Intervention Model:	Single Group Assignment
Number of Arms:	1
Masking:	Open Label

Allocation:	N/A
Endpoint Classification:	Safety/Efficacy Study
Enrollment:	35 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: Methoxy Polyethylene Glycol-Epoetin Beta Participants received methoxy polyethylene glycol-epoetin beta treatment monthly for 36 weeks with an efficacy evaluation period (EEP) during weeks 29-36 and followed by a 4 week follow-up period.	Drug: methoxy polyethylene glycol-epoetin beta 1.2 mcg/kg administered subcutaneously (sc) monthly for 36 weeks (initial recommended dose) Other Names: • Mircera

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age:	18 Years
Maximum Age:	
Gender:	Both
Accepts Healthy Volunteers?:	No
Criteria:	Inclusion Criteria:

- Adult participants, >=18 years of age;
- Chronic renal anemia;
- No ESA therapy during previous 3 months.

Exclusion Criteria:

- Transfusion of red blood cells during previous 2 months;
- Poorly controlled hypertension requiring hospitalization in previous 6 months;
- Significant acute or chronic bleeding.

Contacts/Locations

Study Officials:	Clinical Trials Study Director

Hoffmann-La Roche

Locations: Belgium
Bruxelles, Belgium, 1200

Roeselare, Belgium, 8800

Bonheiden, Belgium, 2820

Genk, Belgium, 3600

Leuven, Belgium, 3000

Edegem, Belgium, 2650

Bruxelles, Belgium, 1000

Liège, Belgium, 4000

Huy, Belgium, 4500

Hornu, Belgium, 7301

Ath, Belgium, 7800

References

Citations:

Links:

Study Data/Documents:

Participant Flow

Reporting Groups

	Description
Methoxy Polyethylene Glycol-Epoetin Beta	Participants received methoxy polyethylene glycol-epoetin beta treatment monthly for 36 weeks with an efficacy evaluation period (EEP) during weeks 29-36 and followed by a 4 week follow-up period. methoxy polyethylene glycol-epoetin beta: 1.2 mcg/kg administered subcutaneously (sc) monthly for 36 weeks (initial recommended dose)

Overall Study

	Methoxy Polyethylene Glycol-Epoetin Beta
Started	35
Completed	21
Not Completed	14
Lost to Follow-up	1
Adverse Event	2
Death	2
Insufficient Therapeutic Response	1
Failure to Return	1
Dialysis Initiation	5
Blood Transfusion	2

Baseline Characteristics

Analysis Population Description

The safety population included all participants who received at least one dose of active drug.

Reporting Groups

	Description
Methoxy Polyethylene Glycol-Epoetin Beta	Participants received methoxy polyethylene glycol-epoetin beta treatment monthly for 36 weeks with an efficacy evaluation period (EEP) during weeks 29-36 and followed by a 4 week follow-up period. methoxy polyethylene glycol-epoetin beta: 1.2 mcg/kg administered subcutaneously (sc) monthly for 36 weeks (initial recommended dose)

Baseline Measures

	Methoxy Polyethylene Glycol-Epoetin Beta
Number of Participants	34
Age, Continuous [units: years] Median (Full Range)	77 (42 to 89)
Gender, Male/Female [units: participants]	
Female	10
Male	24

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Percentage of Participants Maintaining Average Hemoglobin Concentration During Efficacy Evaluation Period (EEP) Within Target Range
Measure Description	The EEP was week 29 through week 36. The target range for average hemoglobin concentration was 10.0 - 12.0 g/dL.
Time Frame	Weeks 29-36
Safety Issue?	No

Analysis Population Description

Intent-to-Treat (ITT) population included all participants who entered the titration period and received active drug.

Reporting Groups

	Description
Methoxy Polyethylene Glycol-Epoetin Beta	Participants received methoxy polyethylene glycol-epoetin beta treatment monthly for 36 weeks with an efficacy evaluation period (EEP) during weeks 29-36 and followed by a 4 week follow-up period. methoxy polyethylene glycol-epoetin beta: 1.2 mcg/kg administered subcutaneously (sc) monthly for 36 weeks (initial recommended dose)

Measured Values

	Methoxy Polyethylene Glycol-Epoetin Beta
Number of Participants Analyzed	34
Percentage of Participants Maintaining Average Hemoglobin Concentration During Efficacy Evaluation Period (EEP) Within Target Range [units: percentage of participants] Number (95% Confidence Interval)	41 (24.7 to 59.3)

2. Secondary Outcome Measure:

Measure Title	Change From Baseline in Hemoglobin Concentration to Efficacy Evaluation Period (EEP)
Measure Description	The mean change Baseline Hemoglobin to the time adjusted average of Hemoglobin during the EEP.
Time Frame	Weeks 0-36
Safety Issue?	No

Analysis Population Description

ITT population included all participants who entered the titration period and received active drug.

Reporting Groups

	Description
Methoxy Polyethylene Glycol-Epoetin Beta	Participants received methoxy polyethylene glycol-epoetin beta treatment monthly for 36 weeks with an efficacy evaluation period (EEP) during weeks 29-36 and followed by a 4 week follow-up period. methoxy polyethylene glycol-epoetin beta: 1.2 mcg/kg administered subcutaneously (sc) monthly for 36 weeks (initial recommended dose)

Measured Values

	Methoxy Polyethylene Glycol-Epoetin Beta
Number of Participants Analyzed	34
Change From Baseline in Hemoglobin Concentration to Efficacy Evaluation Period (EEP) [units: grams/deciliter (g/dL)] Mean (Standard Deviation)	0.99 (1.38)

3. Secondary Outcome Measure:

Measure Title	Percentage of Participants Maintaining Hemoglobin Concentrations Within Range of 10-12 Grams/Deciliter (g/dL) Throughout Efficacy Evaluation Period (EEP)
Measure Description	
Time Frame	Weeks 29-36
Safety Issue?	No

Analysis Population Description

ITT population included all participants who entered the titration period and received active drug.

Reporting Groups

	Description
Methoxy Polyethylene Glycol-Epoetin Beta	Participants received methoxy polyethylene glycol-epoetin beta treatment monthly for 36 weeks with an efficacy evaluation period (EEP) during weeks 29-36 and followed by a 4 week follow-up period. methoxy polyethylene glycol-epoetin beta: 1.2 mcg/kg administered subcutaneously (sc) monthly for 36 weeks (initial recommended dose)

Measured Values

	Methoxy Polyethylene Glycol-Epoetin Beta
Number of Participants Analyzed	34
Percentage of Participants Maintaining Hemoglobin Concentrations Within Range of 10-12 Grams/ Deciliter (g/dL) Throughout Efficacy Evaluation Period (EEP) [units: percentage of participants] Number (95% Confidence Interval)	23.5 (10.8 to 41.2)

4. Secondary Outcome Measure:

Measure Title	Mean Time Spent in Hemoglobin Range of 10-12 g/dL During Efficacy Evaluation Period (EEP)
Measure Description	
Time Frame	Weeks 29-36
Safety Issue?	No

Analysis Population Description

ITT population included all participants who entered the titration period and received active drug.

Reporting Groups

	Description
Methoxy Polyethylene Glycol-Epoetin Beta	Participants received methoxy polyethylene glycol-epoetin beta treatment monthly for 36 weeks with an efficacy evaluation period (EEP) during weeks 29-36 and followed by a 4 week follow-up period. methoxy polyethylene glycol-epoetin beta: 1.2 mcg/kg administered subcutaneously (sc) monthly for 36 weeks (initial recommended dose)

Measured Values

	Methoxy Polyethylene Glycol-Epoetin Beta
Number of Participants Analyzed	34
Mean Time Spent in Hemoglobin Range of 10-12 g/dL During Efficacy Evaluation Period (EEP) [units: days] Mean (Standard Deviation)	28.6 (21.2)

5. Secondary Outcome Measure:

Measure Title	Percentage of Participants With Adverse Events
Measure Description	An adverse event is any untoward medical occurrence in a participant administered a pharmaceutical product and which does not necessarily have to have a causal relationship with the treatment. An adverse event can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding, for example), symptom, or disease temporally associated with the use of a pharmaceutical product, whether or not considered related to the pharmaceutical product. Preexisting conditions which worsen during a study are also considered as adverse events.
Time Frame	Weeks 1-40
Safety Issue?	No

Analysis Population Description

The safety population included all participants who received at least one dose of active drug.

Reporting Groups

	Description
Methoxy Polyethylene Glycol-Epoetin Beta	Participants received methoxy polyethylene glycol-epoetin beta treatment monthly for 36 weeks with an efficacy evaluation period (EEP) during weeks 29-36 and followed by a 4 week follow-up period. methoxy polyethylene glycol-epoetin beta: 1.2 mcg/kg administered subcutaneously (sc) monthly for 36 weeks (initial recommended dose)

Measured Values

	Methoxy Polyethylene Glycol-Epoetin Beta
Number of Participants Analyzed	34
Percentage of Participants With Adverse Events [units: percentage of participants]	97

Reported Adverse Events

Time Frame	Weeks 1-40
Additional Description	[Not specified]

Reporting Groups

	Description
Methoxy Polyethylene Glycol-Epoetin Beta	Participants received methoxy polyethylene glycol-epoetin beta treatment monthly for 36 weeks with an efficacy evaluation period (EEP) during weeks 29-36 and followed by a 4 week follow-up period. methoxy polyethylene glycol-epoetin beta: 1.2 mcg/kg administered subcutaneously (sc) monthly for 36 weeks (initial recommended dose)

Serious Adverse Events

	Methoxy Polyethylene Glycol-Epoetin Beta
	Affected/At Risk (%)
Total	15/34 (44.12%)
Blood and lymphatic system disorders	
Anaemia [A] †	2/34 (5.88%)

	Methoxy Polyethylene Glycol-Epoetin Beta
	Affected/At Risk (%)
Pancytopenia [A] †	1/34 (2.94%)
Cardiac disorders	
Cardiac arrest [A] †	1/34 (2.94%)
Cardiac failure [A] †	2/34 (5.88%)
Cardiac failure congestive [A] †	1/34 (2.94%)
Myocardial infarction [A] †	1/34 (2.94%)
Gastrointestinal disorders	
Diarrhoea [A] †	1/34 (2.94%)
Oesophagitis [A] †	1/34 (2.94%)
General disorders	
Administration related reaction [A] †	1/34 (2.94%)
Asthenia [A] †	1/34 (2.94%)
Medical device complication [A] †	1/34 (2.94%)
Pyrexia [A] †	1/34 (2.94%)
Sudden cardiac death [A] †	1/34 (2.94%)
Hepatobiliary disorders	
Hepatic cirrhosis [A] †	1/34 (2.94%)
Infections and infestations	
Diarrhoea infectious [A] †	1/34 (2.94%)
Gastroenteritis [A] †	1/34 (2.94%)
Pseudomembranous colitis [A] †	1/34 (2.94%)
Urinary tract infection [A] †	1/34 (2.94%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	

	Methoxy Polyethylene Glycol-Epoetin Beta
	Affected/At Risk (%)
Lung neoplasm malignant [A] †	1/34 (2.94%)
Nervous system disorders	
Carotid artery stenosis [A] †	1/34 (2.94%)
Renal and urinary disorders	
Renal failure acute [A] †	1/34 (2.94%)
Renal failure chronic [A] †	2/34 (5.88%)
Respiratory, thoracic and mediastinal disorders	
Lung disorder [A] †	1/34 (2.94%)
Vascular disorders	
Extremity necrosis [A] †	1/34 (2.94%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA (13.0)

Other Adverse Events

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

	Methoxy Polyethylene Glycol-Epoetin Beta
	Affected/At Risk (%)
Total	29/34 (85.29%)
Cardiac disorders	
Atrial fibrillation [A] †	3/34 (8.82%)
Gastrointestinal disorders	
Diarrhoea [A] †	2/34 (5.88%)
Gastric ulcer [A] †	2/34 (5.88%)
Nausea [A] †	2/34 (5.88%)
Oesophagitis [A] †	2/34 (5.88%)

	Methoxy Polyethylene Glycol-Epoetin Beta
	Affected/At Risk (%)
General disorders	
Chest pain [A] †	2/34 (5.88%)
Fatigue [A] †	5/34 (14.71%)
Oedema [A] †	4/34 (11.76%)
Infections and infestations	
Bronchitis [A] †	6/34 (17.65%)
Gastroenteritis [A] †	2/34 (5.88%)
Nasopharyngitis [A] †	3/34 (8.82%)
Injury, poisoning and procedural complications	
Fall [A] †	3/34 (8.82%)
Metabolism and nutrition disorders	
Hyperkalaemia [A] †	2/34 (5.88%)
Musculoskeletal and connective tissue disorders	
Arthralgia [A] †	2/34 (5.88%)
Back pain [A] †	3/34 (8.82%)
Muscle spasms [A] †	2/34 (5.88%)
Nervous system disorders	
Headache [A] †	2/34 (5.88%)
Skin and subcutaneous tissue disorders	
Pruritus [A] †	2/34 (5.88%)
Vascular disorders	
Hypertension [A] †	15/34 (44.12%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA (13.0)

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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