ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
Release Date: 03/08/2016

ClinicalTrials.gov ID: NCT00559637

Study Identification

Unique Protocol ID:	ML20888
Brief Title:	A Study of Subcutaneous Mircera in Participants With Chronic Kidney Disease Not Treated With ESA or on Dialysis (MERCUR)
Official Title:	Single-arm, Open Study to Investigate the Efficacy, Safety and Tolerability of Monthly Subcutaneously Administered C.E.R.A. in Patients With Renal Anemia Not Yet Subject to Dialysis and Not Yet Permanently Treated With ESAs
Secondary IDs:	2007-000126-46 [EudraCT Number]

Study Status

Record Verification:	March 2016
Overall Status:	Completed
Study Start:	January 2008
Primary Completion:	June 2010 [Actual]
Study Completion:	June 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: 95/07_ff Board Name: Ethik-Kommission der Universitaet Wuerzburg Board Affiliation: Unknown Phone: 0049 931 201 53864 Email: Schmidt_S1@klinik.uni-wuerzburg.de
Data Monitoring?:	
Plan to Share Data?:	
Oversight Authorities:	Germany: Paul-Ehrlich-Institut

Study Description

Brief Summary:	This single arm study will assess the efficacy and safety of subcutaneous Mircera for correction of anemia in participants with chronic kidney disease who are not treated with erythropoiesis stimulating agent (ESA) and not on dialysis. Eligible participants will receive Mircera by monthly subcutaneous injections. The initial dose, based on body weight, will be 1.2 micrograms/kilogram (mcg/kg). The anticipated time on study treatment is 9-11 months, and the target sample size is 100-500 individuals.
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:	184 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: Methoxy polyethylene glycol-epoetin beta Methoxy polyethylene glycol-epoetin beta will be administered subcutaneously once a month. The starting dose will be 1.2 mcg/kg of body weight. Further dose adjustments will be performed during the study depending on the hemoglobin value. Total duration of treatment will be 9 months for all participants in the study and up to 11 months for participants who will be shifted to the dialysis.	Drug: Methoxy polyethylene glycol-epoetin beta Methoxy polyethylene glycol-epoetin beta will be administered subcutaneously once a month. The starting dose will be 1.2 mcg/kg of body weight. Further dose adjustments will be performed during the study depending on the hemoglobin value. Total duration of treatment will be 9 months for all participants in the study and up to 11 months for participants who will be shifted to the dialysis. Other Names: • Mircera

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age: 18 Years

Maximum Age:

Gender: Both

Accepts Healthy Volunteers?: No

Criteria: Inclusion Criteria:

- chronic renal anemia;
- hemoglobin value less than or equal to (<=) 10.5 grams/deciliter (g/dL).

Exclusion Criteria:

- prior ESA therapy during previous 3 months;
- acute or chronic bleeding requiring therapy during previous 2 months;
- transfusion of red blood cells during previous 2 months;
- active malignant disease (except non-melanoma skin cancer).

Contacts/Locations

Study Officials: Clinical Trials
Study Director

Hoffmann-La Roche

Locations: Germany

Hoyerswerda, Germany, 02977

Dieburg, Germany, 64807

Arnsberg, Germany, 59759

Wetzlar, Germany, 35578

Dortmund, Germany, 44135

Bonn, Germany, 53179

Düsseldorf, Germany, 40211

Mühlacker, Germany, 75417

ULM, Germany, 89077

Jena, Germany, 07743

Sindelfingen, Germany, 71063

Lörrach, Germany, 79539

Tübingen, Germany, 72076

Rheine, Germany, 48431

Worms, Germany, 67547

Hamburg, Germany, 22391

Hamburg, Germany, 21073

Lübeck, Germany, 23562

Mettmann, Germany, 40822

Lünen, Germany, 44534

Friedberg, Germany, 86316

Sinsheim, Germany, 74889

Tangermünde, Germany, 39590

Wuerzburg, Germany, 97080

Saarlouis, Germany, 66740

Ludwigslust, Germany, 19288

Grimma, Germany, 04668

Bad Aibling, Germany, 83043

Schwandorf, Germany, 92421

Berlin, Germany, 10115

Koeln, Germany, 50937

Mainz, Germany, 55131

Emsdetten, Germany, 48282

Regensburg, Germany, 93053

Zwickau, Germany, 08056

Bischofswerda, Germany, 01877

Trier, Germany, 54290

Köln, Germany, 51109

Velbert, Germany, 42549

Hilden, Germany, 40721

Kaiserslautern, Germany, 67655

München, Germany, 81545

Homburg, Germany, 66424

Heidelberg, Germany, 69120

Schweinfurt, Germany, 97421

Bad Malente, Germany, 23714

Frankfurt, Germany, 60528

Ansbach, Germany, 91522

Würzburg, Germany, 97072

Wiesloch, Germany, 69168

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 once a month. The starting dose was 1.2 micrograms per kilogram (mcg/kg) of body weight. Further dose adjustments were performed during the study depending on the hemoglobin value. Total duration of treatment was 9 months for all participants in the study and up to 11 months if participants were shifted to dialysis.

Overall Study

	Methoxy Polyethylene Glycol-epoetin Beta
Started	184
Completed	130
Not Completed	54
Adverse Event	22
Withdrawal by Subject	4
Protocol Violation	6
Withdrawal criteria fulfilled	4

	Methoxy Polyethylene Glycol-epoetin Beta
Failure to return	6
Insufficient response	3
Started requiring dialysis after month 7	2
Suspected lung cancer	1
Participation in another study	1
Delayed administration of C.E.R.A	1
Change of center	1
Change of home	1
Inclusion or exclusion criteria violated	2

Baseline Characteristics

Analysis Population Description

Safety population included all participants who received at least one dose of study medication.

Reporting Groups

	Description
Methoxy Polyethylene Glycol-epoetin Beta	Methoxy polyethylene glycol-epoetin beta was administered subcutaneously once a month. The starting dose was 1.2 mcg/kg of body weight. Further dose adjustments were performed during the study depending on the hemoglobin value. Total duration of treatment was 9 months for all participants in the study and up to 11 months if participants were shifted to dialysis.

Baseline Measures

	Methoxy Polyethylene Glycol-epoetin Beta
Number of Participants	184
Age, Continuous [units: years] Mean (Standard Deviation)	66.4 (15.77)
Gender, Male/Female [units: participants]	
Female	91
Male	93

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Percentage of Participants With Both Hemoglobin Values of the Evaluation Phase in the Range of 11-12 Grams Per Deciliter (g/dL)
Measure Description	Participants with both hemoglobin values of the evaluation phase (Months 8 and 9, i.e., Study Days 200-260, values were at least 21 days apart) in the range of 11-12 g/dL were classified as responder. Participants who received transfusion of erythrocytes between Study Day 139 and 260, or with at least one value missing or outside the range were classified as non-responder for the hemoglobin-range concerned.
Time Frame	Evaluation phase (Months 8 and 9)
Safety Issue?	No

Analysis Population Description

Intent to treat (ITT) population included all participants who received at least one dose of study medication with at least one hemoglobin value measured during treatment period.

Reporting Groups

	Description
Methoxy Polyethylene Glycol-epoetin Beta	Methoxy polyethylene glycol-epoetin beta was administered subcutaneously once a month. The starting dose was 1.2 mcg/kg of body weight. Further dose adjustments were performed during the study depending on the hemoglobin value. Total duration of treatment was 9 months for all participants in the study and up to 11 months if participants were shifted to dialysis.

Measured Values

	Methoxy Polyethylene Glycol-epoetin Beta
Number of Participants Analyzed	178
Percentage of Participants With Both Hemoglobin Values of the Evaluation Phase in the Range of 11-12 Grams Per Deciliter (g/dL) [units: percentage of participants] Number (95% Confidence Interval)	10.67 (6.55 to 16.17)

2. Primary Outcome Measure:

Measure Title	Percentage of Participants With Both Hemoglobin Values of the Evaluation Phase in the Range of 11-13 g/dL

Measure Description	Participants with both hemoglobin values of the evaluation phase (Months 8 and 9, i.e., Study Days 200-260, values were at least 21 days apart) in the range of 11-13 g/dL were classified as responder. Participants who received transfusion of erythrocytes between Study Day 139 and 260, or with at least one value missing or outside the range were classified as non-responder for the hemoglobin-range concerned.
Time Frame	Evaluation phase (Months 8 and 9)
Safety Issue?	No

Analysis Population Description
ITT population

Reporting Groups

	Description
Methoxy Polyethylene Glycol-epoetin Beta	Methoxy polyethylene glycol-epoetin beta was administered subcutaneously once a month. The starting dose was 1.2 mcg/kg of body weight. Further dose adjustments were performed during the study depending on the hemoglobin value. Total duration of treatment was 9 months for all participants in the study and up to 11 months if participants were shifted to dialysis.

Measured Values

	Methoxy Polyethylene Glycol-epoetin Beta
Number of Participants Analyzed	178
Percentage of Participants With Both Hemoglobin Values of the Evaluation Phase in the Range of 11-13 g/dL [units: percentage of participants] Number (95% Confidence Interval)	29.21 (22.65 to 36.48)

3. Primary Outcome Measure:

Measure Title	Change From Baseline in Hemoglobin Value to the Evaluation Phase
Measure Description	The change from the baseline hemoglobin value to the mean hemoglobin value of the evaluation phase was only calculated if both the baseline value and the mean of the evaluation phase (mean of Months 8 and 9) were available. In case of only one available hemoglobin value within the evaluation phase, that single value replaced the mean.
Time Frame	Baseline, evaluation phase (Months 8 and 9)
Safety Issue?	No

Analysis Population Description
ITT population. Here, number of participants analyzed = participants who were evaluable for this outcome.

Reporting Groups

	Description
Methoxy Polyethylene Glycol-epoetin Beta	Methoxy polyethylene glycol-epoetin beta was administered subcutaneously once a month. The starting dose was 1.2 mcg/kg of body weight. Further dose adjustments were performed during the study depending on the hemoglobin value. Total duration of treatment was 9 months for all participants in the study and up to 11 months if participants were shifted to dialysis.

Measured Values

	Methoxy Polyethylene Glycol-epoetin Beta
Number of Participants Analyzed	131
Change From Baseline in Hemoglobin Value to the Evaluation Phase [units: g/dL] Mean (Standard Deviation)	1.6 (1.10)

4. Secondary Outcome Measure:

Measure Title	Duration of Hemoglobin Values in the Range of 11-12 g/dL
Measure Description	The duration of hemoglobin values staying within the range of 11-12 g/dL was defined as the number of (not necessarily consecutive) months with all corresponding hemoglobin values in the respective range. All months with missing hemoglobin values were counted as months where the hemoglobin value did not stay within the respective range.
Time Frame	Baseline to Month 9
Safety Issue?	No

Analysis Population Description

ITT population

Reporting Groups

	Description
Methoxy Polyethylene Glycol-epoetin Beta	Methoxy polyethylene glycol-epoetin beta was administered subcutaneously once a month. The starting dose was 1.2 mcg/kg of body weight. Further dose adjustments were performed during the study depending on the hemoglobin value. Total duration of treatment was 9 months for all participants in the study and up to 11 months if participants were shifted to dialysis.

Measured Values

	Methoxy Polyethylene Glycol-epoetin Beta
Number of Participants Analyzed	178
Duration of Hemoglobin Values in the Range of 11-12 g/dL [units: months] Mean (Standard Deviation)	2.40 (1.796)

5. Secondary Outcome Measure:

Measure Title	Duration of Hemoglobin Values in the Range of 11-13 g/dL
Measure Description	The duration of hemoglobin values staying within the range of 11-13 g/dL was defined as the number of (not necessarily consecutive) months with all corresponding hemoglobin values in the respective range. All months with missing hemoglobin values were counted as months where the hemoglobin value did not stay within the respective range.
Time Frame	Baseline to Month 9
Safety Issue?	No

Analysis Population Description

ITT population

Reporting Groups

	Description
Methoxy Polyethylene Glycol-epoetin Beta	Methoxy polyethylene glycol-epoetin beta was administered subcutaneously once a month. The starting dose was 1.2 mcg/kg of body weight. Further dose adjustments were performed during the study depending on the hemoglobin value. Total duration of treatment was 9 months for all participants in the study and up to 11 months if participants were shifted to dialysis.

Measured Values

	Methoxy Polyethylene Glycol-epoetin Beta
Number of Participants Analyzed	178
Duration of Hemoglobin Values in the Range of 11-13 g/dL [units: months] Mean (Standard Deviation)	3.62 (2.450)

6. Secondary Outcome Measure:

Measure Title	Time to Increase of Hemoglobin Value to Over 11 g/dL
Measure Description	The duration (number of months) until the hemoglobin value exceeded 11 g/dL for the first time was summarized for participants for whom at least one measured hemoglobin value exceeded 11 g/dL.
Time Frame	Baseline to Month 9
Safety Issue?	No

Analysis Population Description

ITT population. Here, number of participants analyzed = participants who were evaluable for this outcome.

Reporting Groups

	Description
Methoxy Polyethylene Glycol-epoetin Beta	Methoxy polyethylene glycol-epoetin beta was administered subcutaneously once a month. The starting dose was 1.2 mcg/kg of body weight. Further dose adjustments were performed during the study depending on the hemoglobin value. Total duration of treatment was 9 months for all participants in the study and up to 11 months if participants were shifted to dialysis.

Measured Values

	Methoxy Polyethylene Glycol-epoetin Beta
Number of Participants Analyzed	152
Time to Increase of Hemoglobin Value to Over 11 g/dL [units: months] Mean (Standard Deviation)	2.28 (1.649)

7. Secondary Outcome Measure:

Measure Title	Total Number of Dose Adjustments
Measure Description	A dose adjustment was defined as a change versus the preceding dose. It included dose increase, dose reduction and dose interruption. An interruption (no dose given) was always counted as a dose adjustment, regardless of whether or not at the previous time point a dose had been administered. After an interruption a change in the dose relative to the dose given before the interruption was counted as a dose adjustment.
Time Frame	Baseline until Month 8

Safety Issue?	No

Analysis Population Description
ITT population

Reporting Groups

	Description
Methoxy Polyethylene Glycol-epoetin Beta	Methoxy polyethylene glycol-epoetin beta was administered subcutaneously once a month. The starting dose was 1.2 mcg/kg of body weight. Further dose adjustments were performed during the study depending on the hemoglobin value. Total duration of treatment was 9 months for all participants in the study and up to 11 months if participants were shifted to dialysis.

Measured Values

	Methoxy Polyethylene Glycol-epoetin Beta
Number of Participants Analyzed	178
Total Number of Dose Adjustments [units: dose adjustments]	
Total number of dose adjustments	595
Total number of dose increases	249
Total number of dose reductions	210
Total number of dose interruptions	136

8. Secondary Outcome Measure:

Measure Title	Total Number of Red Blood Cell (RBC) Transfusions
Measure Description	RBC transfusions could be given during the study, if medically necessary, i.e., in participants with severe anemia with distinct symptoms or signs of anemia (such as in participants with acute blood loss, with severe angina, or whose hemoglobin decreased to critical levels).
Time Frame	Baseline to Month 9
Safety Issue?	No

Analysis Population Description
ITT population

Reporting Groups

	Description
Methoxy Polyethylene Glycol-epoetin Beta	Methoxy polyethylene glycol-epoetin beta was administered subcutaneously once a month. The starting dose was 1.2 mcg/kg of body weight. Further dose adjustments were performed during the study depending on the hemoglobin value. Total duration of treatment was 9 months for all participants in the study and up to 11 months if participants were shifted to dialysis.

Measured Values

	Methoxy Polyethylene Glycol-epoetin Beta
Number of Participants Analyzed	178
Total Number of Red Blood Cell (RBC) Transfusions [units: number of transfusions]	39

Reported Adverse Events

Time Frame	Baseline to Month 11
Additional Description	Safety population

Reporting Groups

	Description
Methoxy Polyethylene Glycol-epoetin Beta	Methoxy polyethylene glycol-epoetin beta was administered subcutaneously once a month. The starting dose was 1.2 mcg/kg of body weight. Further dose adjustments were performed during the study depending on the hemoglobin value. Total duration of treatment was 9 months for all participants in the study and up to 11 months if participants were shifted to dialysis.

Serious Adverse Events

	Methoxy Polyethylene Glycol-epoetin Beta
	Affected/At Risk (%)
Total	88/184 (47.83%)
Blood and lymphatic system disorders	
Anaemia [A] *	3/184 (1.63%)
Haemorrhagic anaemia [A] *	6/184 (3.26%)

	Methoxy Polyethylene Glycol-epoetin Beta
	Affected/At Risk (%)
Heparin-induced thrombocytopenia [A] *	1/184 (0.54%)
Nephrogenic anaemia [A] *	12/184 (6.52%)
Cardiac disorders	
Angina unstable [A] *	2/184 (1.09%)
Atrial fibrillation [A] *	2/184 (1.09%)
Bradycardia [A] *	1/184 (0.54%)
Cardiac failure [A] *	4/184 (2.17%)
Cardiogenic shock [A] *	1/184 (0.54%)
Myocardial infarction [A] *	1/184 (0.54%)
Pericardial effusion [A] *	1/184 (0.54%)
Tachyarrhythmia [A] *	2/184 (1.09%)
Congenital, familial and genetic disorders	
Congenital cystic kidney disease [A] *	1/184 (0.54%)
Ear and labyrinth disorders	
Vertigo [A] *	1/184 (0.54%)
Eye disorders	
Retinal artery occlusion [A] *	1/184 (0.54%)
Gastrointestinal disorders	
Abdominal hernia [A] *	1/184 (0.54%)
Abdominal pain [A] *	1/184 (0.54%)
Abdominal pain upper [A] *	1/184 (0.54%)
Aphthous stomatitis [A] *	1/184 (0.54%)
Diverticulitis intestinal haemorrhagic [A] *	1/184 (0.54%)

	Methoxy Polyethylene Glycol-epoetin Beta
	Affected/At Risk (%)
Gastric haemorrhage [A] *	1/184 (0.54%)
Gastric ulcer haemorrhage [A] *	2/184 (1.09%)
Haemorrhoidal haemorrhage [A] *	1/184 (0.54%)
General disorders	
Device dislocation [A] *	1/184 (0.54%)
Device malfunction [A] *	1/184 (0.54%)
Drug ineffective [A] *	2/184 (1.09%)
Medical device complication [A] *	2/184 (1.09%)
Oedema [A] *	1/184 (0.54%)
Pyrexia [A] *	1/184 (0.54%)
Immune system disorders	
Anti-neutrophil cytoplasmic antibody positive vasculitis [A] *	1/184 (0.54%)
Kidney transplant rejection [A] *	1/184 (0.54%)
Infections and infestations	
Bronchitis [A] *	1/184 (0.54%)
Bronchopneumonia [A] *	1/184 (0.54%)
Cystitis [A] *	1/184 (0.54%)
Gastroenteritis [A] *	1/184 (0.54%)
Herpes zoster ophthalmic [A] *	1/184 (0.54%)
Meningitis enterococcal [A] *	1/184 (0.54%)
Pneumonia [A] *	1/184 (0.54%)
Postoperative wound infection [A] *	1/184 (0.54%)

	Methoxy Polyethylene Glycol-epoetin Beta
	Affected/At Risk (%)
Sepsis [A] *	3/184 (1.63%)
Tracheobronchitis [A] *	1/184 (0.54%)
Urinary tract infection [A] *	1/184 (0.54%)
Injury, poisoning and procedural complications	
Anaemia postoperative [A] *	2/184 (1.09%)
Drug toxicity [A] *	1/184 (0.54%)
Fall [A] *	1/184 (0.54%)
Femoral neck fracture [A] *	1/184 (0.54%)
Lumbar vertebral fracture [A] *	1/184 (0.54%)
Meniscus lesion [A] *	1/184 (0.54%)
Post procedural haematoma [A] *	1/184 (0.54%)
Post procedural haemorrhage [A] *	1/184 (0.54%)
Shunt occlusion [A] *	5/184 (2.72%)
Traumatic haematoma [A] *	1/184 (0.54%)
Investigations	
Blood pressure increased [A] *	1/184 (0.54%)
Blood sodium decreased [A] *	1/184 (0.54%)
Haemoglobin decreased [A] *	2/184 (1.09%)
Metabolism and nutrition disorders	
Cachexia [A] *	1/184 (0.54%)
Dehydration [A] *	1/184 (0.54%)
Diabetes mellitus [A] *	1/184 (0.54%)

	Methoxy Polyethylene Glycol-epoetin Beta
	Affected/At Risk (%)
Diabetic foot [A] *	1/184 (0.54%)
Diabetic ketoacidosis [A] *	1/184 (0.54%)
Hyperglycaemia [A] *	1/184 (0.54%)
Hyperkalaemia [A] *	1/184 (0.54%)
Hypoglycaemia [A] *	2/184 (1.09%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
Gallbladder cancer [A] *	1/184 (0.54%)
Gastric cancer [A] *	1/184 (0.54%)
Lung squamous cell carcinoma stage unspecified [A] *	1/184 (0.54%)
Nervous system disorders	
Cerebrovascular accident [A] *	1/184 (0.54%)
Hypertensive encephalopathy [A] *	1/184 (0.54%)
Ischaemic stroke [A] *	1/184 (0.54%)
Renal and urinary disorders	
Renal cyst haemorrhage [A] *	1/184 (0.54%)
Renal failure [A] *	27/184 (14.67%)
Renal failure acute [A] *	2/184 (1.09%)
Renal failure chronic [A] *	8/184 (4.35%)
Renal impairment [A] *	5/184 (2.72%)
Respiratory, thoracic and mediastinal disorders	
Chronic obstructive pulmonary disease [A] *	1/184 (0.54%)
Dyspnoea [A] *	1/184 (0.54%)

	Methoxy Polyethylene Glycol-epoetin Beta
	Affected/At Risk (%)
Pleural effusion [A] *	2/184 (1.09%)
Pulmonary embolism [A] *	2/184 (1.09%)
Sleep apnoea syndrome [A] *	1/184 (0.54%)
Skin and subcutaneous tissue disorders	
Rash [A] *	1/184 (0.54%)
Skin ulcer [A] *	2/184 (1.09%)
Vascular disorders	
Deep vein thrombosis [A] *	1/184 (0.54%)
Haematoma [A] *	1/184 (0.54%)
Peripheral arterial occlusive disease [A] *	1/184 (0.54%)
Poor peripheral circulation [A] *	1/184 (0.54%)
Venous thrombosis limb [A] *	1/184 (0.54%)

* Indicates events were collected by non-systematic methods.
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	109/184 (59.24%)
Ear and labyrinth disorders	
Vertigo [A] *	13/184 (7.07%)
Endocrine disorders	
Hyperparathyroidism secondary [A] *	17/184 (9.24%)
Gastrointestinal disorders	

	Methoxy Polyethylene Glycol-epoetin Beta
	Affected/At Risk (%)
Diarrhoea [A] *	12/184 (6.52%)
Nausea [A] *	13/184 (7.07%)
General disorders	
Fatigue [A] *	10/184 (5.43%)
Oedema [A] *	28/184 (15.22%)
Oedema peripheral [A] *	20/184 (10.87%)
Infections and infestations	
Bronchitis [A] *	11/184 (5.98%)
Urinary tract infection [A] *	10/184 (5.43%)
Metabolism and nutrition disorders	
Acidosis [A] *	10/184 (5.43%)
Hyperphosphataemia [A] *	11/184 (5.98%)
Iron deficiency [A] *	13/184 (7.07%)
Musculoskeletal and connective tissue disorders	
Muscle spasms [A] *	13/184 (7.07%)
Vascular disorders	
Hypertension [A] *	56/184 (30.43%)

* Indicates events were collected by non-systematic methods.
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:

Name/Official Title: Medical Communications
Organization: Hoffmann-La Roche
Phone: 800-821-8590
Email: genentech@druginfo.com