ClinicalTrials.gov Protocol and Results Registration System (PRS) Receipt
Release Date: 06/06/2014

Dynepo Infrequent Dosing Study

This study has been terminated.
(The termination of the study is not linked to a product recall or result of any safety signal. Rather it was sponsor's commercial decision to withdraw the MA)

Sponsor:	Shire
Collaborators:	
Information provided by:	Shire
ClinicalTrials.gov Identifier:	NCT00450333

Purpose

The purpose of this study is to demonstrate non-inferiority of efficacy between twice weekly and once weekly dose schedule of Dynepo in previously erythropoietin (EPO)-naive patients, as measured by haemoglobin at week 24 and secondly to demonstrate the non-inferiority of efficacy between once weekly and once every two weeks dose schedules of Dynepo in patients previously stable on EPO, as measured by Hb over Weeks 16 to 24.

Condition	Intervention	Phase
Anemia Kidney Failure	Drug: Dynepo (Epoetin delta) Drug: Dynepo	Phase 3

Study Type: Interventional
Study Design: Treatment, Parallel Assignment, Open Label, Randomized, Safety/Efficacy Study
Official Title: An Open-Label, Phase IIIb, Multi-Centre, Randomised, Parallel-Group Study to Investigate the Efficacy and Safety of Three Dosing Schedules of Subcutaneous Dynepo in Adult Patients With Anaemia Associated With Chronic Kidney Disease Who Are Pre-Dialysis or Require Peritoneal Dialysis or Haemodialysis

Further study details as provided by Shire:

Primary Outcome Measure:

- Change From Baseline in Hemoglobin (Hb) Concentration at 24 Weeks [Time Frame: Baseline and 24 weeks] [Designated as safety issue: Yes]

This study terminated early due to a decision by Shire Pharmaceuticals to permanently cease marketing Dynepo due to commercial reasons, it was not the result of any safety signal. Not enough subjects completed the study to do any efficacy analyses.

Secondary Outcome Measures:

- Number of Patients Who Achieve Hb Levels of > or Equal to 11 g/dL [Time Frame: week 16 and 24] [Designated as safety issue: Yes]
  This study terminated early due to a decision by Shire Pharmaceuticals to permanently cease marketing Dynepo due to commercial reasons, it was not the result of any safety signal. Not enough subjects completed the study to do any efficacy analyses.
- Change From Baseline in Hematocrits at 16 and 24 Weeks [Time Frame: Baseline and Weeks 16 and 24] [Designated as safety issue: Yes]
  This study terminated early due to a decision by Shire Pharmaceuticals to permanently cease marketing Dynepo due to commercial reasons, it was not the result of any safety signal. Not enough subjects completed the study to do any efficacy analyses.

Enrollment: 407
Study Start Date: October 2006
Primary Completion Date: July 2008
Study Completion Date: July 2008

Arms	Assigned Interventions
Active Comparator: 1 Erythropoietin(EPO)-naive BIW	Drug: Dynepo (Epoetin delta) subcutaneous, BIW for 24 weeks
Active Comparator: 2 EPO-naive QW	Drug: Dynepo subcutaneous, QW for 24 weeks
Active Comparator: 3 EPO QW	Drug: Dynepo subcutaneous, QW for 24 weeks
Active Comparator: 4 EPO Q2W	Drug: Dynepo subcutaneous, Q2W for 24 weeks

Eligibility

Ages Eligible for Study: 18 Years and older
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- Aged at least 18 years with chronic kidney disease (Kidney Disease Outcomes Quality Initiative [KDOQI] stage III-V).
- Stable on and taking doses <= 10,000 IU/week of subcutaneous (sc) EPO or requiring initiation of EPO.
- Transferrin saturation >= 20% and ferritin >= 100 ng/mL.

Exclusion Criteria:

- Uncontrolled hypertension.
- Requiring doses of EPO > 10,000 IU/week.

- Two or more doses of prescribed EPO treatment missed ot withheld by physician order in the 14 days immediately prior tp randomisation in the study.
- Active bleeding disorder (diathesis) (for example, Gastrointestinal or Genitourinary tract bleeding).
- Treatment with immunosuppressive drugs (other than corticosteroids for a chronic condition) in the 30 days immediately prior to randomisation in the study.
- Androgen therapy in the 30 days immediately prior to randomisation in the study.
- Known Human Immunodeficiency Virus(HIV)infection.
- History of hypersensitivity to EPO therapy or to any of the excipients of Dynepo.

Contacts and Locations

Locations

Austria

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Leuven, Belgium, B-3000

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Head of Nephrology, Fundacion Puigvert
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Madrid, Spain, 28007
Hospital Central de Asturias
Oviedo, Spain, 33006
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Investigators

Principal Investigator:	Iain C Macdougall, MD	Kings College Hospital, London

More Information

Responsible Party: Shire (Timothy Whitaker, M.D.)
Study ID Numbers: SPD490-301

Study Results

Participant Flow

Recruitment Details	This study was terminated on July 31, 2008 as a result of a decision by Shire Pharmaceutical to permanently cease marketing Dynepo and withdraw the Marketing Authorisation. The decision was for commercial reasons, it was not the result of any safety signal. Not enough subjects completed the study to do any efficacy analyses.
Pre-Assignment Details	Erythropoietin (EPO)-naive subjects were randomized to receive Dynepo (Epoetin delta) once weekly (QW) or twice weekly (BIW) and subjects who were already stable on EPO (doses < or equal to 10,000 IU/week) were randomized to receive Dynepo once every 2 weeks (Q2W) or once weekly.

Reporting Groups

	Description
Dynepo (Epoetin Delta)-Naive Once-weekly (QW)	Erythropoietin(EPO)-naive subjects receiving Epoetin delta once weekly (QW)
Dynepo-naive Twice-weekly (BIW)	EPO-naive subjects receiving Epoetin delta twice weekly (BIW)
Dynepo Once Every 2 Weeks (Q2W)	EPO stable subjects receiving Epoetin delta once every 2 weeks (Q2W)
Dynepo QW	EPO stable subjects receiving Epoetin delta once weekly (QW)

Overall Study

	Dynepo (Epoetin Delta)-Naive Once-weekly (QW)	Dynepo-naive Twice-weekly (BIW)	Dynepo Once Every 2 Weeks (Q2W)	Dynepo QW
Started	98	107	100	102
Completed	44	44	75	74
Not Completed	54	63	25	28
Study terminated	47	54	16	21
Adverse Event	1	7	2	2
Protocol Violation	1	0	1	0
Withdrawal by Subject	1	0	3	0

	Dynepo (Epoetin Delta)-Naive Once-weekly (QW)	Dynepo-naive Twice-weekly (BIW)	Dynepo Once Every 2 Weeks (Q2W)	Dynepo QW
Kidney transplant	1	0	1	3
Death	3	2	2	2

Baseline Characteristics

Reporting Groups

	Description
Dynepo (Epoetin Delta)-Naive Once-weekly (QW)	Erythropoietin(EPO)-naive subjects receiving Epoetin delta once weekly (QW)
Dynepo-naive Twice-weekly (BIW)	EPO-naive subjects receiving Epoetin delta twice weekly (BIW)
Dynepo Once Every 2 Weeks (Q2W)	EPO stable subjects receiving Epoetin delta once every 2 weeks (Q2W)
Dynepo QW	EPO stable subjects receiving Epoetin delta once weekly (QW)

Baseline Measures

	Dynepo (Epoetin Delta)-Naive Once-weekly (QW)	Dynepo-naive Twice-weekly (BIW)	Dynepo Once Every 2 Weeks (Q2W)	Dynepo QW	Total
Number of Participants	98	107	100	102	407
Age, Categorical [units: participants]					
<=18 years	0	0	0	0	0
Between 18 and 65 years	37	35	48	35	155
>=65 years	61	72	52	67	252
Age, Continuous [units: years] Mean (Standard Deviation)	66.2 (14.97)	67.0 (12.45)	64.2 (13.86)	65.5 (16.04)	65.7 (14.33)
Gender, Male/Female [units: participants]					
Female	45	41	33	41	160
Male	53	66	67	61	247
Region of Enrollment					

	Dynepo (Epoetin Delta)-Naive Once-weekly (QW)	Dynepo-naive Twice-weekly (BIW)	Dynepo Once Every 2 Weeks (Q2W)	Dynepo QW	Total
[units: participants]					
France	6	8	8	3	25
Spain	3	2	13	14	32
Belgium	2	2	12	11	27
Austria	3	1	0	0	4
Germany	15	16	15	14	60
United Kingdom	10	15	11	12	48
Italy	5	5	28	35	73
Australia	19	22	7	6	54
Hungary	8	8	0	1	17
Latvia	14	16	4	4	38
Lithuania	10	9	0	0	19
New Zealand	3	3	2	2	10

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Change From Baseline in Hemoglobin (Hb) Concentration at 24 Weeks
Measure Description	This study terminated early due to a decision by Shire Pharmaceuticals to permanently cease marketing Dynepo due to commercial reasons, it was not the result of any safety signal. Not enough subjects completed the study to do any efficacy analyses.
Time Frame	Baseline and 24 weeks
Safety Issue?	Yes

Analysis Population Description

This study terminated early due to a decision by Shire Pharmaceuticals to permanently cease marketing Dynepo due to commercial reasons, it was not the result of any safety signal. Not enough subjects completed the study to do any efficacy analyses.

Reporting Groups

	Description
Dynepo (Epoetin Delta)-Naive Once-weekly (QW)	Erythropoietin(EPO)-naive subjects receiving Epoetin delta once weekly (QW)
Dynepo-naive Twice-weekly (BIW)	EPO-naive subjects receiving Epoetin delta twice weekly (BIW)
Dynepo Once Every 2 Weeks (Q2W)	EPO stable subjects receiving Epoetin delta once every 2 weeks (Q2W)
Dynepo QW	EPO stable subjects receiving Epoetin delta once weekly (QW)

Measured Values

	Dynepo (Epoetin Delta)-Naive Once-weekly (QW)	Dynepo-naive Twice-weekly (BIW)	Dynepo Once Every 2 Weeks (Q2W)	Dynepo QW
Number of Participants Analyzed	0	0	0	0

No data displayed because Outcome Measure has zero total participants analyzed.

2. Secondary Outcome Measure:

Measure Title	Number of Patients Who Achieve Hb Levels of > or Equal to 11 g/dL
Measure Description	This study terminated early due to a decision by Shire Pharmaceuticals to permanently cease marketing Dynepo due to commercial reasons, it was not the result of any safety signal. Not enough subjects completed the study to do any efficacy analyses.
Time Frame	week 16 and 24
Safety Issue?	Yes

Analysis Population Description

This study terminated early due to a decision by Shire Pharmaceuticals to permanently cease marketing Dynepo due to commercial reasons, it was not the result of any safety signal. Not enough subjects completed the study to do any efficacy analyses.

Reporting Groups

	Description
Dynepo (Epoetin Delta)-Naive Once-weekly (QW)	Erythropoietin(EPO)-naive subjects receiving Epoetin delta once weekly (QW)
Dynepo-naive Twice-weekly (BIW)	EPO-naive subjects receiving Epoetin delta twice weekly (BIW)
Dynepo Once Every 2 Weeks (Q2W)	EPO stable subjects receiving Epoetin delta once every 2 weeks (Q2W)
Dynepo QW	EPO stable subjects receiving Epoetin delta once weekly (QW)

Measured Values

	Dynepo (Epoetin Delta)-Naive Once-weekly (QW)	Dynepo-naive Twice-weekly (BIW)	Dynepo Once Every 2 Weeks (Q2W)	Dynepo QW
Number of Participants Analyzed	0	0	0	0

No data displayed because Outcome Measure has zero total participants analyzed.

3. Secondary Outcome Measure:

Measure Title	Change From Baseline in Hematocrits at 16 and 24 Weeks
Measure Description	This study terminated early due to a decision by Shire Pharmaceuticals to permanently cease marketing Dynepo due to commercial reasons, it was not the result of any safety signal. Not enough subjects completed the study to do any efficacy analyses.
Time Frame	Baseline and Weeks 16 and 24
Safety Issue?	Yes

Analysis Population Description

This study terminated early due to a decision by Shire Pharmaceuticals to permanently cease marketing Dynepo due to commercial reasons, it was not the result of any safety signal. Not enough subjects completed the study to do any efficacy analyses.

Reporting Groups

	Description
Dynepo (Epoetin Delta)-Naive Once-weekly (QW)	Erythropoietin(EPO)-naive subjects receiving Epoetin delta once weekly (QW)
Dynepo-naive Twice-weekly (BIW)	EPO-naive subjects receiving Epoetin delta twice weekly (BIW)
Dynepo Once Every 2 Weeks (Q2W)	EPO stable subjects receiving Epoetin delta once every 2 weeks (Q2W)
Dynepo QW	EPO stable subjects receiving Epoetin delta once weekly (QW)

Measured Values

	Dynepo (Epoetin Delta)-Naive Once-weekly (QW)	Dynepo-naive Twice-weekly (BIW)	Dynepo Once Every 2 Weeks (Q2W)	Dynepo QW
Number of Participants Analyzed	0	0	0	0

No data displayed because Outcome Measure has zero total participants analyzed.

Reported Adverse Events

Time Frame	[Not specified]
Additional Description	[Not specified]

Reporting Groups

	Description
Dynepo (Epoetin Delta)-Naive Once-weekly (QW)	Erythropoietin(EPO)-naive subjects receiving Epoetin delta once weekly (QW)
Dynepo-naive Twice-weekly (BIW)	EPO-naive subjects receiving Epoetin delta twice weekly (BIW)
Dynepo Once Every 2 Weeks (Q2W)	EPO stable subjects receiving Epoetin delta once every 2 weeks (Q2W)
Dynepo QW	EPO stable subjects receiving Epoetin delta once weekly (QW)

Serious Adverse Events

	Dynepo (Epoetin Delta)-Naive Once-weekly (QW)	Dynepo-naive Twice-weekly (BIW)	Dynepo Once Every 2 Weeks (Q2W)	Dynepo QW
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	15/98 (15.31%)	23/107 (21.5%)	23/100 (23%)	20/102 (19.61%)
Blood and lymphatic system disorders				
Anemia *	0/98 (0%)	1/107 (0.93%)	0/100 (0%)	0/102 (0%)
DIC *	0/98 (0%)	1/107 (0.93%)	0/100 (0%)	0/102 (0%)
Cardiac disorders				
Acute MI *	0/98 (0%)	1/107 (0.93%)	1/100 (1%)	0/102 (0%)
Acute coronary syndrome *	0/98 (0%)	0/107 (0%)	1/100 (1%)	1/102 (0.98%)
Angina *	0/98 (0%)	2/107 (1.87%)	1/100 (1%)	3/102 (2.94%)
Atrial fibrillation *	0/98 (0%)	1/107 (0.93%)	1/100 (1%)	0/102 (0%)
Cardiac arrest *	1/98 (1.02%)	0/107 (0%)	0/100 (0%)	1/102 (0.98%)
Cardiac failure *	0/98 (0%)	1/107 (0.93%)	1/100 (1%)	2/102 (1.96%)
Coronary artery disease *	1/98 (1.02%)	0/107 (0%)	0/100 (0%)	0/102 (0%)
Ischemic cardiomyopathy *	0/98 (0%)	0/107 (0%)	1/100 (1%)	2/102 (1.96%)
Tachycardia *	1/98 (1.02%)	0/107 (0%)	0/100 (0%)	0/102 (0%)

	Dynepo (Epoetin Delta)-Naive Once-weekly (QW)	Dynepo-naive Twice-weekly (BIW)	Dynepo Once Every 2 Weeks (Q2W)	Dynepo QW
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Gastrointestinal disorders				
Abdominal pain *	0/98 (0%)	1/107 (0.93%)	2/100 (2%)	0/102 (0%)
Colitis *	0/98 (0%)	0/107 (0%)	1/100 (1%)	0/102 (0%)
Diarrhea *	0/98 (0%)	0/107 (0%)	0/100 (0%)	1/102 (0.98%)
Duodenal ulcer hemorrhage *	1/98 (1.02%)	1/107 (0.93%)	0/100 (0%)	0/102 (0%)
Gastrointestinal hemorrhage *	1/98 (1.02%)	1/107 (0.93%)	1/100 (1%)	2/102 (1.96%)
Intestinal fistula *	1/98 (1.02%)	0/107 (0%)	0/100 (0%)	0/102 (0%)
Peritonitis *	3/98 (3.06%)	0/107 (0%)	1/100 (1%)	2/102 (1.96%)
General disorders				
Catheter related complication *	0/98 (0%)	0/107 (0%)	1/100 (1%)	0/102 (0%)
Catheter thrombosis *	1/98 (1.02%)	0/107 (0%)	0/100 (0%)	0/102 (0%)
Infections and infestations				
Catheter related infection *	0/98 (0%)	0/107 (0%)	2/100 (2%)	0/102 (0%)
Pneumonia *	1/98 (1.02%)	2/107 (1.87%)	0/100 (0%)	0/102 (0%)
Pyelonephritis *	0/98 (0%)	1/107 (0.93%)	1/100 (1%)	0/102 (0%)
Sepsis *	1/98 (1.02%)	1/107 (0.93%)	1/100 (1%)	1/102 (0.98%)
Injury, poisoning and procedural complications				
Arteriovenous fistula complication *	1/98 (1.02%)	1/107 (0.93%)	2/100 (2%)	0/102 (0%)
Investigations				
Hemoglobin decreased *	1/98 (1.02%)	0/107 (0%)	0/100 (0%)	0/102 (0%)
Metabolism and nutrition disorders				
Fluid overload *	0/98 (0%)	0/107 (0%)	1/100 (1%)	0/102 (0%)
Musculoskeletal and connective tissue disorders				
Back pain *	1/98 (1.02%)	0/107 (0%)	0/100 (0%)	0/102 (0%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
Lung neoplasm malignant *	0/98 (0%)	1/107 (0.93%)	0/100 (0%)	0/102 (0%)

	Dynepo (Epoetin Delta)-Naive Once-weekly (QW)	Dynepo-naive Twice-weekly (BIW)	Dynepo Once Every 2 Weeks (Q2W)	Dynepo QW
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Nervous system disorders				
Brain stem hemorrhage *	0/98 (0%)	1/107 (0.93%)	0/100 (0%)	0/102 (0%)
Cerebrovascular accident *	0/98 (0%)	1/107 (0.93%)	0/100 (0%)	0/102 (0%)
Hypoglycemic coma *	0/98 (0%)	1/107 (0.93%)	0/100 (0%)	0/102 (0%)
Intercranial hemorrhage *	0/98 (0%)	0/107 (0%)	0/100 (0%)	1/102 (0.98%)
Restless legs syndrome *	0/98 (0%)	0/107 (0%)	1/100 (1%)	0/102 (0%)
Renal and urinary disorders				
Renal failure *	0/98 (0%)	1/107 (0.93%)	0/100 (0%)	1/102 (0.98%)
Respiratory, thoracic and mediastinal disorders				
Orthopnea *	0/98 (0%)	0/107 (0%)	1/100 (1%)	0/102 (0%)
Pulmonary edema *	0/98 (0%)	1/107 (0.93%)	0/100 (0%)	0/102 (0%)
Vascular disorders				
Arterial occlusive disease *	0/98 (0%)	1/107 (0.93%)	0/100 (0%)	0/102 (0%)
Hemorrhage *	1/98 (1.02%)	0/107 (0%)	0/100 (0%)	0/102 (0%)
Hypertension *	0/98 (0%)	2/107 (1.87%)	2/100 (2%)	2/102 (1.96%)
Hypotension *	1/98 (1.02%)	0/107 (0%)	0/100 (0%)	0/102 (0%)
Peripheral ischemia *	0/98 (0%)	1/107 (0.93%)	0/100 (0%)	0/102 (0%)
Thrombosis *	0/98 (0%)	0/107 (0%)	0/100 (0%)	1/102 (0.98%)

* Indicates events were collected by non-systematic methods.

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

	Dynepo (Epoetin Delta)-Naive Once-weekly (QW)	Dynepo-naive Twice-weekly (BIW)	Dynepo Once Every 2 Weeks (Q2W)	Dynepo QW
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	59/98 (60.2%)	50/107 (46.73%)	44/100 (44%)	44/102 (43.14%)
Gastrointestinal disorders				
Diarrhea *	5/98 (5.1%)	3/107 (2.8%)	3/100 (3%)	4/102 (3.92%)

	Dynepo (Epoetin Delta)-Naive Once-weekly (QW)	Dynepo-naive Twice-weekly (BIW)	Dynepo Once Every 2 Weeks (Q2W)	Dynepo QW
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Nausea *	6/98 (6.12%)	2/107 (1.87%)	2/100 (2%)	2/102 (1.96%)
General disorders				
Edema peripheral *	5/98 (5.1%)	5/107 (4.67%)	2/100 (2%)	3/102 (2.94%)
Infections and infestations				
Bronchitis *	2/98 (2.04%)	4/107 (3.74%)	8/100 (8%)	4/102 (3.92%)
Influenza *	5/98 (5.1%)	1/107 (0.93%)	0/100 (0%)	4/102 (3.92%)
Metabolism and nutrition disorders				
Hyperkalemia *	7/98 (7.14%)	1/107 (0.93%)	0/100 (0%)	2/102 (1.96%)
Hyperphosphatemia *	5/98 (5.1%)	5/107 (4.67%)	3/100 (3%)	1/102 (0.98%)
Iron deficiency *	5/98 (5.1%)	2/107 (1.87%)	0/100 (0%)	0/102 (0%)
Musculoskeletal and connective tissue disorders				
Back pain *	7/98 (7.14%)	2/107 (1.87%)	2/100 (2%)	2/102 (1.96%)
Muscle spasms *	0/98 (0%)	2/107 (1.87%)	2/100 (2%)	6/102 (5.88%)
Pain in extremity *	1/98 (1.02%)	0/107 (0%)	5/100 (5%)	2/102 (1.96%)
Nervous system disorders				
Headache *	3/98 (3.06%)	8/107 (7.48%)	4/100 (4%)	2/102 (1.96%)
Respiratory, thoracic and mediastinal disorders				
Cough *	1/98 (1.02%)	4/107 (3.74%)	5/100 (5%)	3/102 (2.94%)
Vascular disorders				
Hypertension *	6/98 (6.12%)	9/107 (8.41%)	3/100 (3%)	6/102 (5.88%)
Hypotension *	1/98 (1.02%)	2/107 (1.87%)	5/100 (5%)	3/102 (2.94%)

* Indicates events were collected by non-systematic methods.

Limitations and Caveats

This study terminated early due to a decision by Shire Pharmaceuticals to permanently cease marketing Dynepo due to commercial reasons, it was not the result of any safety signal. Not enough subjects completed the study to do any efficacy analyses.

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.

If a multicenter publication is not submitted within twelve (12) months after conclusion, abandonment or termination of the Study at all sites, or after Sponsor confirms there shall be no multicenter Study publication, the Institution and/or such Principal Investigator may publish the results from the Institution site individually.

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