Trial record **1 of 1** for: EPOANE3018
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A Study Evaluating Epoetin Alfa 40,000 IU (International Units) Every Week or 80,000 IU Every Week Compared to Placebo in Patients With Low or Intermediate-1 Risk Myelodysplastic Syndromes at Risk for Transfusion

This study has been terminated.

(The study was stopped due to low subject enrollment. No safety issue or other concern factored into this decision.)

Sponsor:
Johnson & Johnson Pharmaceutical Research & Development, L.L.C.

Collaborator:
Centocor Ortho Biotech Services, L.L.C.

Information provided by:
Johnson & Johnson Pharmaceutical Research & Development, L.L.C.

ClinicalTrials.gov Identifier:
NCT00695396

First received: June 5, 2008
Last updated: October 2, 2012
Last verified: October 2012
History of Changes

Full Text View | Tabular View | Study Results | Disclaimer | How to Read a Study Record

Results First Received: February 8, 2011

Study Type:	Interventional
	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study;

Study Design:	Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Caregiver, Investigator); Primary Purpose: Treatment
Conditions:	Myelodysplastic Syndromes Anemia
Interventions:	Drug: Placebo Drug: Epoetin alfa

Participant Flow

Hide Participant Flow

Recruitment Details

Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations
No text entered.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
No text entered.

Reporting Groups

	Description
Placebo	(1ml or 2 mL) subcutaneously once every week
Epoetin Alfa 40000 IU	(1 mL) subcutaneously once every week
Epoetin Alfa 80000 IU	(2 mL) subcutaneously once every week

Participant Flow: Overall Study

	Placebo	**Epoetin Alfa 40000 IU**	**Epoetin Alfa 80000 IU**

STARTED	**8**	**8**	**9**
COMPLETED	**1**	**0**	**1**
NOT COMPLETED	**7**	**8**	**8**
Study Closed Prematurely	**5**	**6**	**8**
Withdrawal by Subject	**2**	**2**	**0**

Baseline Characteristics

Hide Baseline Characteristics

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
No text entered.

Reporting Groups

	Description
Placebo	(1ml or 2 mL) subcutaneously once every week
Epoetin Alfa 40000 IU	(1 mL) subcutaneously once every week
Epoetin Alfa 80000 IU	(2 mL) subcutaneously once every week
Total	Total of all reporting groups

Baseline Measures

	Placebo	**Epoetin Alfa 40000 IU**	**Epoetin Alfa 80000 IU**	**Total**
Number of Participants [units: participants]	**8**	**8**	**9**	**25**

Age [units: participants]				
<=18 years	**0**	**0**	**0**	**0**
Between 18 and 65 years	**1**	**1**	**2**	**4**
>=65 years	**7**	**7**	**7**	**21**
Age [units: years] Mean (Standard Deviation)	**73 (10.52)**	**77.3 (9.78)**	**67.7 (9.89)**	**72.4 (10.44)**
Gender [units: participants]				
Female	**2**	**3**	**7**	**12**
Male	**6**	**5**	**2**	**13**
Region of Enrollment [units: participants]				
CANADA	**1**	**0**	**0**	**1**
ITALY	**0**	**1**	**0**	**1**
RUSSIA	**2**	**0**	**4**	**6**
USA	**5**	**7**	**5**	**17**

Outcome Measures

Hide All Outcome Measures

1. Primary: Red Blood Cell (RBC) Transfusion [Time Frame: Approximately 48 weeks]

Measure Type	Primary

Measure Title	Red Blood Cell (RBC) Transfusion
Measure Description	Incidence of participants who received at least 1 Red Blood Cell (RBC) transfusion during the study (from randomization through the end of study)
Time Frame	Approximately 48 weeks
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The intent-to-treat (ITT) population was defined as all participants randomly assigned to a treatment group, regardless of whether they received any treatment.

Reporting Groups

	Description
Placebo	(1ml or 2 mL) subcutaneously once every week
Epoetin Alfa 40000 IU	(1 mL) subcutaneously once every week
Epoetin Alfa 80000 IU	(2 mL) subcutaneously once every week

Measured Values

	Placebo	**Epoetin Alfa 40000 IU**	**Epoetin Alfa 80000 IU**
Number of Participants Analyzed [units: participants]	**8**	**8**	**9**
Red Blood Cell (RBC) Transfusion [units: participants]	**5**	**3**	**1**

No statistical analysis provided for Red Blood Cell (RBC) Transfusion

2. Secondary: RBC Transfusion From Day 29 Through the End of Study [Time Frame: Day 29 through the end of study (approximately 48 weeks)]

Measure Type	Secondary
Measure Title	RBC Transfusion From Day 29 Through the End of Study
Measure Description	incidence of participants who received at least 1 RBC transfusion from Day 29 through the end of study (approximately 48 weeks).
Time Frame	Day 29 through the end of study (approximately 48 weeks)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The intent-to-treat (ITT) population was defined as all participants randomly assigned to a treatment group, regardless of whether they received any treatment.

Reporting Groups

	Description
Placebo	(1ml or 2 mL) subcutaneously once every week
Epoetin Alfa 40000 IU	(1 mL) subcutaneously once every week
Epoetin Alfa 80000 IU	(2 mL) subcutaneously once every week

Measured Values

	Placebo	**Epoetin Alfa 40000 IU**	**Epoetin Alfa 80000 IU**
Number of Participants Analyzed [units: participants]	**8**	**8**	**9**

RBC Transfusion From Day 29 Through the End of Study [units: participants]	**4**	**2**	**1**

No statistical analysis provided for RBC Transfusion From Day 29 Through the End of Study

3. Secondary: Transfusion Dependent [Time Frame: Approximately 48 weeks]

Measure Type	Secondary
Measure Title	Transfusion Dependent
Measure Description	Participants who were transfusion-dependent were those who received 4 or more RBC units during a consecutive 8-week period.
Time Frame	Approximately 48 weeks
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The intent-to-treat (ITT) population.

Reporting Groups

	Description
Placebo	(1ml or 2 mL) subcutaneously once every week
Epoetin Alfa 40000 IU	(1 mL) subcutaneously once every week
Epoetin Alfa 80000 IU	(2 mL) subcutaneously once every week

Measured Values

	Placebo	Epoetin Alfa 40000 IU	Epoetin Alfa 80000 IU
Number of Participants Analyzed [units: participants]	**8**	**8**	**9**
Transfusion Dependent [units: participants]	**2**	**2**	**1**

No statistical analysis provided for Transfusion Dependent

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	No text entered.
Additional Description	No text entered.

Reporting Groups

	Description
Placebo	(1ml or 2 mL) subcutaneously once every week
Epoetin Alfa 40000 IU	(1 mL) subcutaneously once every week
Epoetin Alfa 80000 IU	(2 mL) subcutaneously once every week

Serious Adverse Events

	Placebo	Epoetin Alfa 40000 IU	Epoetin Alfa 80000 IU
Total, serious adverse events			
# participants affected / at risk	**2/8 (25.00%)**	**2/8 (25.00%)**	**4/9 (44.44%)**
Blood and lymphatic system disorders			

Aplasia Pure Red Cell [*1]			
# participants affected / at risk	**1/8 (12.50%)**	**0/8 (0.00%)**	**0/9 (0.00%)**
Anaemia [*1]			
# participants affected / at risk	**0/8 (0.00%)**	**0/8 (0.00%)**	**1/9 (11.11%)**
Splenomegaly [*1]			
# participants affected / at risk	**0/8 (0.00%)**	**0/8 (0.00%)**	**1/9 (11.11%)**
Eye disorders			
Vision Blurred [*1]			
# participants affected / at risk	**0/8 (0.00%)**	**1/8 (12.50%)**	**0/9 (0.00%)**
Gastrointestinal disorders			
Gastrointestinal Haemorrhage [*1]			
# participants affected / at risk	**0/8 (0.00%)**	**1/8 (12.50%)**	**0/9 (0.00%)**
General disorders			
Asthenia [*1]			
# participants affected / at risk	**0/8 (0.00%)**	**1/8 (12.50%)**	**0/9 (0.00%)**
Injury, poisoning and procedural complications			
Humerus Fracture [*1]			
# participants affected / at risk	**0/8 (0.00%)**	**0/8 (0.00%)**	**1/9 (11.11%)**
Wrist Fracture [*1]			
# participants affected / at risk	**0/8 (0.00%)**	**0/8 (0.00%)**	**1/9 (11.11%)**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Prostate Cancer [*1]			
# participants affected / at risk	**1/8 (12.50%)**	**0/8 (0.00%)**	**0/9 (0.00%)**
Skin and subcutaneous tissue disorders			

Hyperhidrosis * 1			
# participants affected / at risk	**0/8 (0.00%)**	**1/8 (12.50%)**	**0/9 (0.00%)**

* Events were collected by non-systematic assessment

1 Term from vocabulary, 'MedDRA 12.1'

Other Adverse Events

Hide Other Adverse Events

Time Frame	No text entered.
Additional Description	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	5

Reporting Groups

	Description
Placebo	(1ml or 2 mL) subcutaneously once every week
Epoetin Alfa 40000 IU	(1 mL) subcutaneously once every week
Epoetin Alfa 80000 IU	(2 mL) subcutaneously once every week

Other Adverse Events

	Placebo	**Epoetin Alfa 40000 IU**	**Epoetin Alfa 80000 IU**
Total, other (not including serious) adverse events			
# participants affected / at risk	**7/8 (87.50%)**	**4/8 (50.00%)**	**6/9 (66.67%)**
Blood and lymphatic system disorders			

Anaemia [*1]			
# participants affected / at risk	**2/8 (25.00%)**	**0/8 (0.00%)**	**0/9 (0.00%)**
Leukopenia [*1]			
# participants affected / at risk	**1/8 (12.50%)**	**0/8 (0.00%)**	**0/9 (0.00%)**
Neutropenia [*1]			
# participants affected / at risk	**1/8 (12.50%)**	**1/8 (12.50%)**	**0/9 (0.00%)**
Leukocytosis [*1]			
# participants affected / at risk	**0/8 (0.00%)**	**1/8 (12.50%)**	**0/9 (0.00%)**
Cardiac disorders			
Palpitations [*1]			
# participants affected / at risk	**0/8 (0.00%)**	**0/8 (0.00%)**	**1/9 (11.11%)**
Gastrointestinal disorders			
Abdominal Discomfort [*1]			
# participants affected / at risk	**1/8 (12.50%)**	**0/8 (0.00%)**	**0/9 (0.00%)**
Diarrhoea [*1]			
# participants affected / at risk	**1/8 (12.50%)**	**1/8 (12.50%)**	**0/9 (0.00%)**
Haematochezia [*1]			
# participants affected / at risk	**1/8 (12.50%)**	**0/8 (0.00%)**	**0/9 (0.00%)**
Oral Pain [*1]			
# participants affected / at risk	**1/8 (12.50%)**	**0/8 (0.00%)**	**0/9 (0.00%)**
Rectal Haemorrhage [*1]			
# participants affected / at risk	**1/8 (12.50%)**	**0/8 (0.00%)**	**0/9 (0.00%)**
Abdominal Pain Upper [*1]			
# participants affected / at risk	**0/8 (0.00%)**	**1/8 (12.50%)**	**0/9 (0.00%)**
Dyspepsia [*1]			

# participants affected / at risk	0/8 (0.00%)	1/8 (12.50%)	0/9 (0.00%)
Nausea [*1]			
# participants affected / at risk	0/8 (0.00%)	1/8 (12.50%)	2/9 (22.22%)
Vomiting [*1]			
# participants affected / at risk	0/8 (0.00%)	1/8 (12.50%)	0/9 (0.00%)
General disorders			
Fatigue [*1]			
# participants affected / at risk	2/8 (25.00%)	2/8 (25.00%)	1/9 (11.11%)
Asthenia [*1]			
# participants affected / at risk	1/8 (12.50%)	0/8 (0.00%)	2/9 (22.22%)
Hyperthermia [*1]			
# participants affected / at risk	0/8 (0.00%)	0/8 (0.00%)	1/9 (11.11%)
Oedema Peripheral [*1]			
# participants affected / at risk	0/8 (0.00%)	1/8 (12.50%)	1/9 (11.11%)
Pyrexia [*1]			
# participants affected / at risk	0/8 (0.00%)	1/8 (12.50%)	0/9 (0.00%)
Hepatobiliary disorders			
Cholelithiasis [*1]			
# participants affected / at risk	0/8 (0.00%)	0/8 (0.00%)	1/9 (11.11%)
Immune system disorders			
Hypersensitivity [*1]			
# participants affected / at risk	0/8 (0.00%)	1/8 (12.50%)	0/9 (0.00%)
Infections and infestations			
Respiratory Tract Infection [*1]			

# participants affected / at risk	0/8 (0.00%)	0/8 (0.00%)	1/9 (11.11%)
Upper Respiratory Tract Infection [*1]			
# participants affected / at risk	0/8 (0.00%)	2/8 (25.00%)	1/9 (11.11%)
Injury, poisoning and procedural complications			
Contusion [*1]			
# participants affected / at risk	1/8 (12.50%)	0/8 (0.00%)	0/9 (0.00%)
Investigations			
Blood Urine Present [*1]			
# participants affected / at risk	0/8 (0.00%)	0/8 (0.00%)	1/9 (11.11%)
Metabolism and nutrition disorders			
Decreased Appetite [*1]			
# participants affected / at risk	0/8 (0.00%)	0/8 (0.00%)	1/9 (11.11%)
Nervous system disorders			
Dizziness [*1]			
# participants affected / at risk	2/8 (25.00%)	0/8 (0.00%)	1/9 (11.11%)
Somnolence [*1]			
# participants affected / at risk	1/8 (12.50%)	0/8 (0.00%)	0/9 (0.00%)
Psychiatric disorders			
Insomnia [*1]			
# participants affected / at risk	1/8 (12.50%)	1/8 (12.50%)	0/9 (0.00%)
Renal and urinary disorders			
Pollakiuria [*1]			
# participants affected / at risk	1/8 (12.50%)	0/8 (0.00%)	0/9 (0.00%)
Respiratory, thoracic and mediastinal disorders			

Dyspnoea * 1			
# participants affected / at risk	**2/8 (25.00%)**	**1/8 (12.50%)**	**1/9 (11.11%)**
Dyspnoea Exertional * 1			
# participants affected / at risk	**0/8 (0.00%)**	**1/8 (12.50%)**	**0/9 (0.00%)**
Productive Cough * 1			
# participants affected / at risk	**0/8 (0.00%)**	**1/8 (12.50%)**	**0/9 (0.00%)**
Skin and subcutaneous tissue disorders			
Rash * 1			
# participants affected / at risk	**0/8 (0.00%)**	**0/8 (0.00%)**	**1/9 (11.11%)**
Vascular disorders			
Hypertension * 1			
# participants affected / at risk	**0/8 (0.00%)**	**1/8 (12.50%)**	**0/9 (0.00%)**

* Events were collected by non-systematic assessment

1 Term from vocabulary, 'MedDRA 12.1'

Limitations and Caveats

Hide Limitations and Caveats

Limitations of the study, such as early termination leading to small numbers of participants analyzed and technical problems with measurement leading to unreliable or uninterpretable data
Because this study was terminated prematurely due to slow enrollment, only limited data were collected. No formal statistical testing was performed. Only descriptive statistics were provided.

More Information

Hide More Information

Certain Agreements:

Principal Investigators are **NOT** employed by the organization sponsoring the study.
There is **NOT** an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

Results Point of Contact:

Name/Title: Senior Director, Head of Hematology and Nephrology
Organization: Johnson & Johnson Pharmaceutical Research & Development, L.L.C.
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Responsible Party:	CDTL PROCURIT/EPREX, Johnson & Johnson Pharmaceutical Research and Development, L.L.C.
ClinicalTrials.gov Identifier:	NCT00695396 History of Changes
Other Study ID Numbers:	CR013651
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Health Authority:	United States: Food and Drug Administration