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Trial record **1 of 1** for: EPOANE4008

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A Safety Study of Epoetin Alfa in Patients With Cancer Who Have Chemotherapy-Related Anemia

This study has been completed.

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

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

ClinicalTrials.gov Identifier:
NCT01394991

First received: September 10, 2010
Last updated: April 3, 2012
Last verified: April 2012
History of Changes

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Results First Received: September 10, 2010

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety Study; Intervention Model: Parallel Assignment; Masking: Open Label; Primary Purpose: Treatment
Conditions:	Anemia Neoplasms
Interventions:	Drug: Epoetin alfa 450 IU/kg once a week Drug: Epoetin alfa 150 IU/kg 3 times a week Drug: Epoetin alfa 450 IU/kg once a week (QW) Drug: Epoetin alfa 150 IU/kg 3 times a week (TIW)

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
This is a randomized, open-label, multicenter study evaluating thrombovascular events in participants with cancer receiving chemotherapy and administered Epoetin Alfa once weekly (QW) or three times a week (TIW) for the treatment of anemia.

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
Epoetin Alfa QW	epoetin alfa at an initial dosage of 450 IU/kg once a week (QW)
Epoetin Alfa TIW	epoetin alfa at an initial dosage of 150 IU/kg 3 times a week (TIW)

Participant Flow: Overall Study

	Epoetin Alfa QW	Epoetin Alfa TIW
STARTED	**242**	**262**

COMPLETED	**183**	**190**
NOT COMPLETED	**59**	**72**
Adverse Event	**0**	**4**
Lack of Efficacy	**5**	**7**
Lost to Follow-up	**6**	**8**
Physician Decision	**1**	**3**
Protocol Violation	**1**	**1**
Withdrawal by Subject	**20**	**17**
Chemotherapy Termination	**10**	**15**
Disease Progression	**7**	**7**
Prematurely Termination of Trial	**9**	**10**

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
Epoetin Alfa QW	epoetin alfa at an initial dosage of 450 IU/kg once a week (QW)
Epoetin Alfa TIW	epoetin alfa at an initial dosage of 150 IU/kg 3 times a week (TIW)
Total	Total of all reporting groups

Baseline Measures

	Epoetin Alfa QW	**Epoetin Alfa TIW**	**Total**
Number of Participants [units: participants]	**242**	**262**	**504**
Age [units: participants]			
<=18 years	**1**	**1**	**2**
Between 18 and 65 years	**160**	**173**	**333**
>=65 years	**81**	**88**	**169**
Age [units: years] Mean (Standard Deviation)	**58.8 (13.35)**	**57.5 (13.53)**	**58.1 (13.44)**
Gender [units: participants]			
Female	**156**	**181**	**337**
Male	**86**	**81**	**167**
Region of Enrollment [units: participants]			

Bulgaria	**6**	**7**	**13**
France	**7**	**6**	**13**
Germany	**51**	**55**	**106**
Great Britain	**1**	**4**	**5**
Greece	**8**	**12**	**20**
Italy	**13**	**13**	**26**
Poland	**7**	**6**	**13**
Romania	**21**	**20**	**41**
Russia	**88**	**93**	**181**
Slovakia	**9**	**11**	**20**
Ukraine	**31**	**35**	**66**

Outcome Measures

Hide All Outcome Measures

1. Primary: Number of Participants With at Least 1 Clinically Relevant and Objectively Confirmed Thrombovascular Event From Randomization Through Week 16 [Time Frame: from randomization through Week 16]

Measure Type	Primary
Measure Title	Number of Participants With at Least 1 Clinically Relevant and Objectively Confirmed Thrombovascular Event From Randomization Through Week 16
Measure Description	Clinically relevant and objectively confirmed thrombovascular event (TVE) was determined by the Adjudication Committee from randomization through Week 16. Clinically relevant TVEs were defined as deep vein thrombosis (DVT) of the limbs; thromboses of other major veins; pulmonary embolism (PE);acute coronary syndrome (ACS);ischemic stroke of arterial or cardiac origin; cerebral venous thrombosis; and arterial thrombosis. Objectively confirmed was defined as the confirmation of the clinical diagnosis of a TVE by appropriate medical imaging studies and laboratory tests.
Time Frame	from randomization through Week 16
Safety Issue	Yes

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 modified intent-to-treat (mITT) population was defined to include all randomized participants who received at least 1 dose of study drug.

Reporting Groups

	Description
Epoetin Alfa QW	epoetin alfa at an initial dosage of 450 IU/kg once a week (QW)
Epoetin Alfa TIW	epoetin alfa at an initial dosage of 150 IU/kg 3 times a week (TIW)

Measured Values

	Epoetin Alfa QW	**Epoetin Alfa TIW**
Number of Participants Analyzed [units: participants]	**242**	**262**
Number of Participants With at Least 1 Clinically Relevant and Objectively Confirmed Thrombovascular Event From Randomization Through Week 16 [units: particpants]	**5**	**10**

Statistical Analysis 1 for Number of Participants With at Least 1 Clinically Relevant and Objectively Confirmed Thrombovascular Event From Randomization Through Week 16

Groups [1]	All groups
Method [2]	Chi-squared
P Value [3]	0.248
Risk Difference (RD) [4]	-0.018
95% Confidence Interval	-0.051 to 0.016

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	The primary hypothesis was that the group of participants receiving epoetin alfa QW and the group of participants receiving epoetin alfa TIW would have similar incidence rate of participants with at least 1 clinically relevant and objectively confirmed TVE from randomization through Week 16.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 2 for Number of Participants With at Least 1 Clinically Relevant and Objectively Confirmed Thrombovascular Event From Randomization Through Week 16

Groups [1]	All groups
Method [2]	Regression, Logistic
P Value [3]	0.254
Odds Ratio (OR) [4]	0.53
95% Confidence Interval	0.18 to 1.58

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

2. Secondary: Number of Positively Adjudicated Thrombovascular Events [Time Frame: during the study (randomization through week 26)]

Measure Type	Secondary

Measure Title	Number of Positively Adjudicated Thrombovascular Events
Measure Description	The number of participants who have at least 1 clinically relevant and objectively confirmed (adjudicated) thrombovascular event (TVE) during the study.
Time Frame	during the study (randomization through week 26)
Safety Issue	Yes

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 modified intent-to-treat (mITT) population used for safety analysis population included all randomized participants who received at least 1 dose of study drug.

Reporting Groups

	Description
Epoetin Alfa QW	epoetin alfa at an initial dosage of 450 IU/kg once a week (QW)
Epoetin Alfa TIW	epoetin alfa at an initial dosage of 150 IU/kg 3 times a week (TIW)

Measured Values

	Epoetin Alfa QW	Epoetin Alfa TIW
Number of Participants Analyzed [units: participants]	**242**	**262**
Number of Positively Adjudicated Thrombovascular Events [units: participants]	**5**	**13**

Statistical Analysis 1 for Number of Positively Adjudicated Thrombovascular Events

Groups [1]	All groups
Method [2]	Chi-squared
P Value [3]	0.08
Risk Difference (RD) [4]	-0.029
95% Confidence Interval	-0.065 to 0.007

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

3. Secondary: Time to First Positively Adjudicated Thrombovascular Event [Time Frame: during the study (randomization through week 26)]

Measure Type	Secondary

Measure Title	Time to First Positively Adjudicated Thrombovascular Event
Measure Description	Analysis of time to first positively adjudicated thrombovascular event (TVE) measured from the date of randomization to the date of the first clinically relevant and objectively confirmed TVE as determined by the Adjudication Committee. Median time is non-estimable because of too few events, incidence was reported instead.
Time Frame	during the study (randomization through week 26)
Safety Issue	Yes

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.
All randomized participants who received at least 1 dose of study drug.

Reporting Groups

	Description
Epoetin Alfa QW	epoetin alfa at an initial dosage of 450 IU/kg once a week (QW)
Epoetin Alfa TIW	epoetin alfa at an initial dosage of 150 IU/kg 3 times a week (TIW)

Measured Values

	Epoetin Alfa QW	**Epoetin Alfa TIW**
Number of Participants Analyzed [units: participants]	**242**	**262**
Time to First Positively Adjudicated Thrombovascular Event [units: participants]	**5**	**13**

Statistical Analysis 1 for Time to First Positively Adjudicated Thrombovascular Event

Groups [1]	All groups
Method [2]	Log Rank
P Value [3]	0.073
Hazard Ratio (HR) [4]	0.40
95% Confidence Interval	0.14 to 1.13

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	The stratified log-rank test accounting for ECOG performance status (0 or 1 versus 2) was used to compare the difference between treatment groups.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	The Cox regression model with covariates for treatment group and Eastern Cooperative Oncology Group (ECOG) performance status (0 or 1 versus 2) was used for estimates of hazard ratio and its 95% confidence interval.

4. Secondary: Number of Suspected Thrombovascular Events [Time Frame: during the study (randomization through week 26)]

Measure Type	Secondary
Measure Title	Number of Suspected Thrombovascular Events
Measure Description	Number of participants who have at least 1 suspected thrombovascular events (TVEs) during the entire study. Suspected TVEs were defined as suspected TVEs during the entire study, whether clinically relevant and objectively confirmed by the Adjudication Committee or not, whether confirmed by the investigator or not.
Time Frame	during the study (randomization through week 26)
Safety Issue	Yes

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.
All randomized participants who received at least 1 dose of study drug.

Reporting Groups

	Description
Epoetin Alfa QW	epoetin alfa at an initial dosage of 450 IU/kg once a week (QW)
Epoetin Alfa TIW	epoetin alfa at an initial dosage of 150 IU/kg 3 times a week (TIW)

Measured Values

	Epoetin Alfa QW	**Epoetin Alfa TIW**
Number of Participants Analyzed [units: participants]	**242**	**262**
Number of Suspected Thrombovascular Events [units: participants]	**9**	**20**

Statistical Analysis 1 for Number of Suspected Thrombovascular Events

Groups [1]	All groups
Method [2]	Chi-squared
P Value [3]	0.059
Risk Difference (RD) [4]	-0.039
95% Confidence Interval	-0.083 to 0.005

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

5. Secondary: Time to First Suspected Thrombovascular Event [Time Frame: during the study (randomization through week 26)]

Measure Type	Secondary
Measure Title	Time to First Suspected Thrombovascular Event
Measure Description	Analysis of time to first suspected thrombovascular event (TVE) measured from the date of randomization to the date of the first suspected TVE during the study. Median time is non-estimable because of too few events, incidence was reported instead.
Time Frame	during the study (randomization through week 26)
Safety Issue	Yes

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.
All randomized participants who received at least 1 dose of study drug.

Reporting Groups

	Description
Epoetin Alfa QW	epoetin alfa at an initial dosage of 450 IU/kg once a week (QW)
Epoetin Alfa TIW	epoetin alfa at an initial dosage of 150 IU/kg 3 times a week (TIW)

Measured Values

	Epoetin Alfa QW	Epoetin Alfa TIW
Number of Participants Analyzed [units: participants]	**242**	**262**
Time to First Suspected Thrombovascular Event [units: participants]	**9**	**20**

Statistical Analysis 1 for Time to First Suspected Thrombovascular Event

Groups [1]	All groups
Method [2]	Log Rank
P Value [3]	0.054
Hazard Ratio (HR) [4]	0.47
95% Confidence Interval	0.21 to 1.03

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	The stratified log-rank test accounting for ECOG score status (0 or 1 versus 2) was used to compare the difference between treatment groups.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	The Cox regression model including covariates for treatment group and the Eastern Cooperative Oncology Group (ECOG) score status (0 or 1 versus 2) was used for estimates of a hazard ratio and its 95% confidence interval.

6. Secondary: Mortality [Time Frame: during the study (randomization through week 26)]

Measure Type	Secondary
Measure Title	Mortality
Measure Description	Number of participants who died during the study.
Time Frame	during the study (randomization through week 26)
Safety Issue	Yes

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.
All randomized participants who received at least 1 dose of study drug.

Reporting Groups

	Description
Epoetin Alfa QW	epoetin alfa at an initial dosage of 450 IU/kg once a week (QW)
Epoetin Alfa TIW	epoetin alfa at an initial dosage of 150 IU/kg 3 times a week (TIW)

Measured Values

	Epoetin Alfa QW	**Epoetin Alfa TIW**
Number of Participants Analyzed [units: participants]	**242**	**262**
Mortality [units: participants]	**25**	**26**

Statistical Analysis 1 for Mortality

Groups [1]	All groups
Method [2]	Chi-squared
P Value [3]	0.88
Risk Difference (RD) [4]	0.0041
95% Confidence Interval	-0.0526 to 0.0608

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

7. Secondary: Number of Hemoglobin Responders [Time Frame: during the study (randomization through week 26)]

Measure Type	Secondary
Measure Title	Number of Hemoglobin Responders
Measure Description	Hemoglobin response was defined as a hemoglobin increase of ≥2 g/dL from baseline or reaching a hemoglobin concentration of 12 g/dL, regardless of dose adjustment.
Time Frame	during the study (randomization through week 26)
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.
All participants who were randomized, regardless of whether or not they received study drug.

Reporting Groups

	Description
Epoetin Alfa QW	epoetin alfa at an initial dosage of 450 IU/kg once a week (QW)
Epoetin Alfa TIW	epoetin alfa at an initial dosage of 150 IU/kg 3 times a week (TIW)

Measured Values

	Epoetin Alfa QW	**Epoetin Alfa TIW**
Number of Participants Analyzed [units: participants]	**242**	**262**
Number of Hemoglobin Responders [units: participants]	**179**	**187**

Statistical Analysis 1 for Number of Hemoglobin Responders

Groups [1]	All groups
Method [2]	Chi-squared
P Value [3]	0.514
Risk Difference (RD) [4]	0.026
95% Confidence Interval	-0.056 to 0.108

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

8. Secondary: Red Blood Cell Transfusions [Time Frame: during the study (randomization through week 26)]

Measure Type	Secondary
Measure Title	Red Blood Cell Transfusions
Measure Description	The number of participants who received at least 1 red blood cell (RBC) transfusion (packed RBC or whole blood) during the study.
Time Frame	during the study (randomization through week 26)
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.
All participants who were randomized, regardless of whether or not they received study drug.

Reporting Groups

	Description
Epoetin Alfa QW	epoetin alfa at an initial dosage of 450 IU/kg once a week (QW)
Epoetin Alfa TIW	epoetin alfa at an initial dosage of 150 IU/kg 3 times a week (TIW)

Measured Values

	Epoetin Alfa QW	**Epoetin Alfa TIW**
Number of Participants Analyzed [units: participants]	**242**	**262**
Red Blood Cell Transfusions [units: participants]	**38**	**42**

Statistical Analysis 1 for Red Blood Cell Transfusions

Groups [1]	All groups
Method [2]	Chi-squared
P Value [3]	0.920
Risk Difference (RD) [4]	-0.003
95% Confidence Interval	-0.071 to 0.065

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

Serious Adverse Events

Hide Serious Adverse Events

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

Reporting Groups

	Description
Epoetin Alfa QW	epoetin alfa at an initial dosage of 450 IU/kg once a week (QW)
Epoetin Alfa TIW	epoetin alfa at an initial dosage of 150 IU/kg 3 times a week (TIW)

Serious Adverse Events

	Epoetin Alfa QW	Epoetin Alfa TIW
Total, serious adverse events		
# participants affected / at risk	**53/242 (21.90%)**	**64/262 (24.43%)**
Blood and lymphatic system disorders		
Anaemia [*1]		
# participants affected / at risk	**4/242 (1.65%)**	**2/262 (0.76%)**
Febrile neutropenia [*1]		
# participants affected / at risk	**4/242 (1.65%)**	**0/262 (0.00%)**
Leukopenia [*1]		
# participants affected / at risk	**3/242 (1.24%)**	**1/262 (0.38%)**
Neutropenia [*1]		
# participants affected / at risk	**2/242 (0.83%)**	**3/262 (1.15%)**
Pancytopenia [*1]		
# participants affected / at risk	**2/242 (0.83%)**	**1/262 (0.38%)**
Thrombocytopenia [*1]		
# participants affected / at risk	**1/242 (0.41%)**	**4/262 (1.53%)**
Cardiac disorders		
Cardiogenic shock [*1]		
# participants affected / at risk	**1/242 (0.41%)**	**0/262 (0.00%)**
Cardiopulmonary failure [*1]		
# participants affected / at risk	**1/242 (0.41%)**	**1/262 (0.38%)**
Angina pectoris [*1]		
# participants affected / at risk	**0/242 (0.00%)**	**1/262 (0.38%)**
Cardiac failure [*1]		
# participants affected / at risk	**0/242 (0.00%)**	**1/262 (0.38%)**
Congestive cardiomyopathy [*1]		
# participants affected / at risk	**0/242 (0.00%)**	**1/262 (0.38%)**
Myocardial infarction [*1]		
# participants affected / at risk	**0/242 (0.00%)**	**1/262 (0.38%)**
Congenital, familial and genetic disorders		
Aplasia [*1]		
# participants affected / at risk	**0/242 (0.00%)**	**1/262 (0.38%)**
Gastrointestinal disorders		
Subileus [*1]		

# participants affected / at risk	**2/242 (0.83%)**	**0/262 (0.00%)**
Vomiting [*1]		
# participants affected / at risk	**2/242 (0.83%)**	**1/262 (0.38%)**
Ascites [*1]		
# participants affected / at risk	**1/242 (0.41%)**	**0/262 (0.00%)**
Diarrhoea [*1]		
# participants affected / at risk	**1/242 (0.41%)**	**0/262 (0.00%)**
Gastric ulcer haemorrhage [*1]		
# participants affected / at risk	**1/242 (0.41%)**	**0/262 (0.00%)**
Mesenteric artery thrombosis [*1]		
# participants affected / at risk	**1/242 (0.41%)**	**0/262 (0.00%)**
Abdominal pain lower [*1]		
# participants affected / at risk	**0/242 (0.00%)**	**1/262 (0.38%)**
Constipation [*1]		
# participants affected / at risk	**0/242 (0.00%)**	**1/262 (0.38%)**
Dysphagia [*1]		
# participants affected / at risk	**0/242 (0.00%)**	**1/262 (0.38%)**
Ileus [*1]		
# participants affected / at risk	**0/242 (0.00%)**	**1/262 (0.38%)**
Intestinal obstruction [*1]		
# participants affected / at risk	**0/242 (0.00%)**	**1/262 (0.38%)**
Odynophagia [*1]		
# participants affected / at risk	**0/242 (0.00%)**	**1/262 (0.38%)**
Oesophageal stenosis [*1]		
# participants affected / at risk	**0/242 (0.00%)**	**1/262 (0.38%)**
Small intestinal obstruction [*1]		
# participants affected / at risk	**0/242 (0.00%)**	**1/262 (0.38%)**
General disorders		
General physical health deterioration [*1]		
# participants affected / at risk	**2/242 (0.83%)**	**1/262 (0.38%)**
Asthenia [*1]		
# participants affected / at risk	**1/242 (0.41%)**	**0/262 (0.00%)**
Fatigue [*1]		
# participants affected / at risk	**1/242 (0.41%)**	**0/262 (0.00%)**
Multi-organ failure [*1]		
# participants affected / at risk	**1/242 (0.41%)**	**0/262 (0.00%)**
Pyrexia [*1]		
# participants affected / at risk	**1/242 (0.41%)**	**1/262 (0.38%)**
Chest pain [*1]		
# participants affected / at risk	**0/242 (0.00%)**	**2/262 (0.76%)**
Death [*1]		
# participants affected / at risk	**0/242 (0.00%)**	**1/262 (0.38%)**
Localised oedema [*1]		
# participants affected / at risk	**0/242 (0.00%)**	**1/262 (0.38%)**

Pain [*1]		
# participants affected / at risk	**0/242 (0.00%)**	**1/262 (0.38%)**
Sudden cardiac death [*1]		
# participants affected / at risk	**0/242 (0.00%)**	**1/262 (0.38%)**
Hepatobiliary disorders		
Acute hepatic failure [*1]		
# participants affected / at risk	**0/242 (0.00%)**	**1/262 (0.38%)**
Cholangitis [*1]		
# participants affected / at risk	**0/242 (0.00%)**	**1/262 (0.38%)**
Immune system disorders		
Hypersensitivity [*1]		
# participants affected / at risk	**1/242 (0.41%)**	**0/262 (0.00%)**
Infections and infestations		
Pneumonia [*1]		
# participants affected / at risk	**2/242 (0.83%)**	**9/262 (3.44%)**
Abscess jaw [*1]		
# participants affected / at risk	**1/242 (0.41%)**	**0/262 (0.00%)**
Bronchitis [*1]		
# participants affected / at risk	**1/242 (0.41%)**	**0/262 (0.00%)**
Endocarditis [*1]		
# participants affected / at risk	**1/242 (0.41%)**	**0/262 (0.00%)**
Escherichia urinary tract infection [*1]		
# participants affected / at risk	**1/242 (0.41%)**	**0/262 (0.00%)**
Herpes zoster [*1]		
# participants affected / at risk	**1/242 (0.41%)**	**0/262 (0.00%)**
Sepsis [*1]		
# participants affected / at risk	**1/242 (0.41%)**	**2/262 (0.76%)**
Septic shock [*1]		
# participants affected / at risk	**1/242 (0.41%)**	**0/262 (0.00%)**
Abdominal wall abscess [*1]		
# participants affected / at risk	**0/242 (0.00%)**	**1/262 (0.38%)**
Bronchopneumonia [*1]		
# participants affected / at risk	**0/242 (0.00%)**	**1/262 (0.38%)**
Erysipeloid [*1]		
# participants affected / at risk	**0/242 (0.00%)**	**1/262 (0.38%)**
Gastrointestinal infection [*1]		
# participants affected / at risk	**0/242 (0.00%)**	**1/262 (0.38%)**
Kidney infection [*1]		
# participants affected / at risk	**0/242 (0.00%)**	**1/262 (0.38%)**
Pneumonia primary atypical [*1]		
# participants affected / at risk	**0/242 (0.00%)**	**1/262 (0.38%)**
Pyelonephritis [*1]		
# participants affected / at risk	**0/242 (0.00%)**	**1/262 (0.38%)**
Urinary tract infection [*1]		

# participants affected / at risk	0/242 (0.00%)	1/262 (0.38%)
Injury, poisoning and procedural complications		
Drug toxicity * 1		
# participants affected / at risk	1/242 (0.41%)	0/262 (0.00%)
Pubic rami fracture * 1		
# participants affected / at risk	0/242 (0.00%)	1/262 (0.38%)
Stent occlusion * 1		
# participants affected / at risk	0/242 (0.00%)	1/262 (0.38%)
Metabolism and nutrition disorders		
Anorexia * 1		
# participants affected / at risk	1/242 (0.41%)	0/262 (0.00%)
Cachexia * 1		
# participants affected / at risk	1/242 (0.41%)	0/262 (0.00%)
Hyperkalaemia * 1		
# participants affected / at risk	1/242 (0.41%)	0/262 (0.00%)
Tumour lysis syndrome * 1		
# participants affected / at risk	1/242 (0.41%)	0/262 (0.00%)
Musculoskeletal and connective tissue disorders		
Muscle spasms * 1		
# participants affected / at risk	1/242 (0.41%)	0/262 (0.00%)
Pain in extremity * 1		
# participants affected / at risk	1/242 (0.41%)	0/262 (0.00%)
Arthralgia * 1		
# participants affected / at risk	0/242 (0.00%)	1/262 (0.38%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Malignant neoplasm progression * 1		
# participants affected / at risk	19/242 (7.85%)	20/262 (7.63%)
Nervous system disorders		
Syncope * 1		
# participants affected / at risk	1/242 (0.41%)	0/262 (0.00%)
Cerebrovascular accident * 1		
# participants affected / at risk	0/242 (0.00%)	2/262 (0.76%)
Spinal cord compression * 1		
# participants affected / at risk	0/242 (0.00%)	1/262 (0.38%)
Renal and urinary disorders		
Renal failure acute * 1		
# participants affected / at risk	1/242 (0.41%)	1/262 (0.38%)
Hydronephrosis * 1		
# participants affected / at risk	0/242 (0.00%)	2/262 (0.76%)
Renal failure * 1		
# participants affected / at risk	0/242 (0.00%)	1/262 (0.38%)
Respiratory, thoracic and mediastinal disorders		
Dyspnoea * 1		

# participants affected / at risk	2/242 (0.83%)	1/262 (0.38%)
Acute respiratory failure * 1		
# participants affected / at risk	1/242 (0.41%)	0/262 (0.00%)
Haemoptysis * 1		
# participants affected / at risk	1/242 (0.41%)	0/262 (0.00%)
Pleural effusion * 1		
# participants affected / at risk	1/242 (0.41%)	0/262 (0.00%)
Pneumothorax * 1		
# participants affected / at risk	1/242 (0.41%)	0/262 (0.00%)
Pulmonary oedema * 1		
# participants affected / at risk	1/242 (0.41%)	0/262 (0.00%)
Respiratory failure * 1		
# participants affected / at risk	1/242 (0.41%)	1/262 (0.38%)
Pulmonary embolism * 1		
# participants affected / at risk	0/242 (0.00%)	4/262 (1.53%)
Vascular disorders		
Deep vein thrombosis * 1		
# participants affected / at risk	3/242 (1.24%)	4/262 (1.53%)
Hypotension * 1		
# participants affected / at risk	1/242 (0.41%)	0/262 (0.00%)
Hypovolaemic shock * 1		
# participants affected / at risk	1/242 (0.41%)	0/262 (0.00%)
Thrombosis * 1		
# participants affected / at risk	1/242 (0.41%)	0/262 (0.00%)
Venous thrombosis * 1		
# participants affected / at risk	1/242 (0.41%)	2/262 (0.76%)
Venous thrombosis limb * 1		
# participants affected / at risk	1/242 (0.41%)	1/262 (0.38%)
Cardiovascular insufficiency * 1		
# participants affected / at risk	0/242 (0.00%)	1/262 (0.38%)
Peripheral arterial occlusive disease * 1		
# participants affected / at risk	0/242 (0.00%)	1/262 (0.38%)
Thrombophlebitis * 1		
# participants affected / at risk	0/242 (0.00%)	1/262 (0.38%)

* Events were collected by non-systematic assessment
1 Term from vocabulary, MEDDRA 12.0

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
Epoetin Alfa QW	epoetin alfa at an initial dosage of 450 IU/kg once a week (QW)
Epoetin Alfa TIW	epoetin alfa at an initial dosage of 150 IU/kg 3 times a week (TIW)

Other Adverse Events

	Epoetin Alfa QW	Epoetin Alfa TIW
Total, other (not including serious) adverse events		
# participants affected / at risk	**157/242 (64.88%)**	**151/262 (57.63%)**
Blood and lymphatic system disorders		
Neutropenia * 1		
# participants affected / at risk	**81/242 (33.47%)**	**72/262 (27.48%)**
Thrombocytopenia * 1		
# participants affected / at risk	**52/242 (21.49%)**	**54/262 (20.61%)**
Leukopenia * 1		
# participants affected / at risk	**51/242 (21.07%)**	**44/262 (16.79%)**
Gastrointestinal disorders		
Nausea * 1		
# participants affected / at risk	**27/242 (11.16%)**	**40/262 (15.27%)**
Diarrhoea * 1		
# participants affected / at risk	**26/242 (10.74%)**	**10/262 (3.82%)**
Vomiting * 1		
# participants affected / at risk	**13/242 (5.37%)**	**24/262 (9.16%)**
General disorders		
Asthenia * 1		
# participants affected / at risk	**21/242 (8.68%)**	**14/262 (5.34%)**
Fatigue * 1		
# participants affected / at risk	**17/242 (7.02%)**	**16/262 (6.11%)**
Pyrexia * 1		
# participants affected / at risk	**15/242 (6.20%)**	**18/262 (6.87%)**
Metabolism and nutrition disorders		
Anorexia * 1		
# participants affected / at risk	**13/242 (5.37%)**	**11/262 (4.20%)**
Respiratory, thoracic and mediastinal disorders		
Dyspnoea * 1		
# participants affected / at risk	**13/242 (5.37%)**	**7/262 (2.67%)**

* Events were collected by non-systematic assessment

1 Term from vocabulary, MEDDRA 12.0

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
No text entered.

More Information

Hide More Information

Certain Agreements:

Principal Investigators are **NOT** employed by the organization sponsoring the study.
There **IS** 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.
The agreement is: ☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **less than or equal to 60 days**. The sponsor cannot require changes to the communication and cannot extend the embargo. ☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **more than 60 days but less than or equal to 180 days**. The sponsor cannot require changes to the communication and cannot extend the embargo. Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed. ☑ **Restriction Description:** Generally, the only disclosure restriction on the PI is that the sponsor has 60 days to review results communications prior to public release and can embargo communications regarding trial results for a period that does not exceed 180 days from the time submitted to the sponsor for review. The sponsor cannot require changes to the communication and cannot extend the embargo.

Results Point of Contact:

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Responsible Party:	Senior Director, CDTL PROCRIT/EPREX, Johnson & Johnson Pharmaceutical Research and Development, L.L.C.
ClinicalTrials.gov Identifier:	NCT01394991 History of Changes
Other Study ID Numbers:	CR010543 **EPOANE4008**
Study First Received:	September 10, 2010
Results First Received:	September 10, 2010
Last Updated:	April 3, 2012
Health Authority:	United States: Institutional Review Board Ukraine: State Pharmacological Center - Ministry of Health

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