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Home > Find Studies > Search Results > Study Record Detail
Text Size

Trial record **1 of 1** for: NCT00924781
Previous Study | Return to List | Next Study

A Study of the Efficacy and Safety of MK2578 for the Treatment of Anemia in Patients With Kidney Disease (MK2578-003-AM03-EXT12)

This study has been terminated.

Sponsor:
Merck Sharp & Dohme Corp.

Information provided by (Responsible Party):
Merck Sharp & Dohme Corp.

ClinicalTrials.gov Identifier:
NCT00924781

First received: June 18, 2009
Last updated: October 30, 2015
Last verified: October 2015
History of Changes

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

Purpose

This study will evaluate the efficacy and safety of intravenous MK2578, given as maintenance treatment for renal anemia in chronic kidney disease patients on dialysis who were previously receiving erythropoietin stimulating agents.

Condition	Intervention	Phase
Anemia Chronic Kidney Disease	Drug: MK2578 1mcg for every 600 Units (U) of Epogen® (epoetin alfa) received per week at Baseline Drug: MK2578 1 mcg for every 350 U of Epogen (epoetin alfa) received per week at Baseline Drug: MK2578 1 mcg for every 200 U of Epogen (epoetin alfa) received per week at Baseline	Phase 2

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Safety/Efficacy Study
Intervention Model: Parallel Assignment
Masking: Open Label
Primary Purpose: Treatment

Official Title: A Phase II Randomized, Open-Label, Multiple-Rising Dose Clinical Trial to Study the Efficacy and Safety of MK2578 for the Maintenance of Anemia Treatment in Patients With Chronic Kidney Disease Who Are on Hemodialysis.

Resource links provided by NLM:

MedlinePlus related topics: Anemia Chronic Kidney Disease Kidney Diseases

Drug Information available for: Epoetin Alfa

U.S. FDA Resources

Further study details as provided by Merck Sharp & Dohme Corp.:

Primary Outcome Measures:

- Change From Baseline in Hemoglobin (Hg) Level at Week 4 [Time Frame: 4 weeks] [Designated as safety issue: No]
- Number of Participants With Composite Events of Death, Myocardial Infarction (MI), and Cerebrovascular Accident (CVA) [Time Frame: 12 weeks] [Designated as safety issue: Yes]
- Number of Participants With Composite Events of Transfusion-Related Adverse Experiences [Time Frame: 12 weeks] [Designated as safety issue: Yes]
- Number of Participants With Composite Events of Infusion Reactions [Time Frame: 12 weeks] [Designated as safety issue: Yes]
- Number of Participants With Events of Death, MI, CVA, Peripheral Vascular Thromboses, Vascular Access Thrombosis, Congestive Heart Failure (CHF), Hypertension, Seizure, or Pure Red Cell Aplasia [Time Frame: 12 weeks] [Designated as safety issue: Yes]
- Number of Participants With Confirmed, Treatment Emergent Antibodies to MK2578 [Time Frame: 12 weeks] [Designated as safety issue: Yes]

Secondary Outcome Measures:

- Change From Baseline in Hg Level at Week 12 [Time Frame: 12 weeks] [Designated as safety issue: No]

Enrollment:	39
Study Start Date:	June 2009
Study Completion Date:	May 2010
Primary Completion Date:	April 2010 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: MK2578 1 mcg for every 600 U of Epogen at Baseline Participants were randomized to receive treatment every week (QW).	Drug: MK2578 1mcg for every 600 Units (U) of Epogen® (epoetin alfa) received per week at Baseline MK2578 was to be administered intravenously (IV). Participants in Cohort 1 were to receive 1 mcg of MK2578 for every 600 U of Epogen (epoetin alfa) received per week at Baseline. Participants were to be randomized to every week (QW) or once every 4 weeks (QM) dosing schedules within each cohort.
Experimental: 1 mcg of MK2578 for every 600 U of Epogen at Baseline Participants were randomized to receive treatment QM.	Drug: MK2578 1mcg for every 600 Units (U) of Epogen® (epoetin alfa) received per week at Baseline MK2578 was to be administered intravenously (IV). Participants in Cohort 1 were to receive 1 mcg of MK2578 for every 600 U of Epogen (epoetin alfa) received per week at Baseline. Participants were to be randomized to every week (QW) or once every 4 weeks (QM) dosing schedules within each cohort.
Experimental: MK2578 1 mcg for every 350 U of Epogen at Baseline Participants were randomized to receive treatment QW.	Drug: MK2578 1 mcg for every 350 U of Epogen (epoetin alfa) received per week at Baseline MK2578 was to be administered IV. Participants in Cohort 2 were to receive 1 mcg of MK2578 for every 350 U of Epogen (epoetin alfa) received per week at Baseline. Participants were to be randomized to QW or QM dosing schedules within each cohort.
Experimental: 1 mcg of MK2578 for every 350 U of Epogen at Baseline Participants were randomized to receive treatment QM.	Drug: MK2578 1 mcg for every 350 U of Epogen (epoetin alfa) received per week at Baseline MK2578 was to be administered IV. Participants in Cohort 2 were to receive 1 mcg of MK2578 for every 350 U of Epogen (epoetin alfa) received per week at Baseline. Participants were to be randomized to QW or QM dosing schedules within each cohort.
Experimental: MK2578 1 mcg for every 200 U of Epogen at Baseline Participants were randomized to receive treatment QW.	Drug: MK2578 1 mcg for every 200 U of Epogen (epoetin alfa) received per week at Baseline MK2578 was to be administered IV. Participants in Cohort 3 were to receive 1 mcg of MK2578 for every 200 U of Epogen (epoetin alfa) received per week at Baseline. Participants were to be randomized to QW or QM dosing schedules within each cohort.
Experimental: 1 mcg of MK2578 for every 200 U	Drug: MK2578 1 mcg for every 200 U of Epogen (epoetin alfa) received per week at Baseline MK2578 was to be administered IV. Participants in Cohort 3 were to receive 1 mcg of MK2578 for every 200 U of

of Epogen at Baseline Participants were randomized to receive treatment QM.	Epogen (epoetin alfa) received per week at Baseline. Participants were to be randomized to QW or QM dosing schedules within each cohort.

Detailed Description:

This study consists of a 12-week base study (MK2578-003-AM03) and an optional 40-week extension study (MK2578-003-EXT12). Participants who complete 12 weeks of treatment in the base study will enter the extension on the most recent dose administered in the base study or a newly adjusted dose, if adjustment is required to bring Hg levels within range. Participants' doses of MK2578 will be adjusted upward or downward during the extension study to maintain Hb in the range of 10-12 g/dL.

Eligibility

Ages Eligible for Study: 18 Years to 70 Years
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

Base Study:

- Patient is male or is a female who either cannot have children or who agrees to use appropriate contraceptive measures
- Patient has been on hemodialysis for at least 6 months when informed consent is signed
- Patient has received intravenous epoetin alfa or epoetin beta for a least 6 months when the informed consent is signed

Extension Study:

- Patient completed the base study through Week 12
- Patient tolerated MK2578 and demonstrated compliance with study procedures

Exclusion Criteria:

- Patient has a life expectancy of less than 6 months
- Patient is scheduled for a kidney transplant within the next 6 months
- Patient has had a blood transfusion within 12 weeks of screening
- Patient has had major surgery within 12 weeks of screening or plans to have surgery
- Patient has Human Immunodeficiency Virus (HIV)
- Patient has history of blood dyscrasia, hematologic disorders or any other disease known to cause anemia
- Patient has severe congestive heart failure (CHF)
- Patient has a history of malignant cancer, except certain skin or cervical cancers
- Patient has a history of grand mal seizures within the last 6 months

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT00924781

Sponsors and Collaborators

Merck Sharp & Dohme Corp.

Investigators

Study Director: Medical Monitor Merck Sharp & Dohme Corp.

More Information

Responsible Party: Merck Sharp & Dohme Corp.

ClinicalTrials.gov Identifier: NCT00924781 History of Changes
Other Study ID Numbers: 2578-003 2009_603
Study First Received: June 18, 2009
Results First Received: October 25, 2011
Last Updated: October 30, 2015
Health Authority: United States: Food and Drug Administration

Keywords provided by Merck Sharp & Dohme Corp.:
Anemia associated with chronic kidney disease (CKD)
Hemodialysis

Additional relevant MeSH terms:

Anemia
Kidney Diseases
Renal Insufficiency, Chronic
Hematologic Diseases
Renal Insufficiency
Urologic Diseases

Epoetin alfa
Hematinics
Hematologic Agents
Pharmacologic Actions
Therapeutic Uses

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TO TOP

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Text Size

Trial record **1 of 1** for: NCT00924781
Previous Study | Return to List | Next Study

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First received: June 18, 2009
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History of Changes

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

Results First Received: October 25, 2011

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Open Label; Primary Purpose: Treatment
Conditions:	Anemia Chronic Kidney Disease
Interventions:	Drug: MK2578 1mcg for every 600 Units (U) of Epogen® (epoetin alfa) received per week at Baseline Drug: MK2578 1 mcg for every 350 U of Epogen (epoetin alfa) received per week at Baseline Drug: MK2578 1 mcg for every 200 U of Epogen (epoetin alfa) received per week at Baseline

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
Participants were recruited from 46 centers (9 centers in Bulgaria, 27 in United States, 3 in Romania, 4 in Italy, and 3 in Poland).

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
At randomization, participants received either MK2578 or matching placebo on Day 1 and crossed over to the alternate treatment at the next dialysis treatment on Day 3.

Reporting Groups

	Description
MK2578 1mcg/600 U or 1 mcg/350 U QW	MK2578 was administered intravenously (IV) QW. Participants were randomized to receive 1 mcg of MK2578 for every 350 Units (U) of Epogen (epoetin alfa) received per week at Baseline.
MK2578 1mcg/600 U or 1 mg/350 U QM	MK2578 was administered IV QM. Participants were randomized to receive 1 mcg of MK2578 for every 600 Units (U) of Epogen (epoetin alfa) or 350 units of Epogen (epoetin alpha) received per week at Baseline.

Participant Flow: Overall Study

	MK2578 1mcg/600 U or 1 mcg/350 U QW	MK2578 1mcg/600 U or 1 mg/350 U QM
STARTED	**20**	**19**
COMPLETED	**8**	**9**
NOT COMPLETED	**12**	**10**
Study terminated by sponsor	**12**	**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
MK2578 1mcg/600U QW	MK2578 IV administered QW.
MK2578 1mcg/600U QM	MK2578 IV administered QM.
MK2578 1mcg/350U QW	MK2578 IV administered QW.
MK2578 1mcg/350U QM	MK2578 IV administered QM.
Total	Total of all reporting groups

Baseline Measures

	MK2578 1mcg/600U QW	MK2578 1mcg/600U QM	MK2578 1mcg/350U QW	MK2578 1mcg/350U QM	Total
Number of Participants [units: participants]	**16**	**15**	**4**	**4**	**39**
Age [units: years] Mean (Standard	**46.3 (14.29)**	**51.7 (10.22)**	**58.0 (8.91)**	**60.5 (4.51)**	**51.0 (12.30)**

Deviation)					
Gender [units: participants]					
Female	**10**	**8**	**3**	**3**	**24**
Male	**6**	**7**	**1**	**1**	**15**

Outcome Measures

Hide All Outcome Measures

1. Primary: Change From Baseline in Hemoglobin (Hg) Level at Week 4 [Time Frame: 4 weeks]

Measure Type	Primary
Measure Title	Change From Baseline in Hemoglobin (Hg) Level at Week 4
Measure Description	No text entered.
Time Frame	4 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.
Full analysis set

Reporting Groups

	Description
MK2578 1mcg/600U QW	MK2578 IV was administered QW. Participants were randomized to receive 1 mcg of MK2578 for every 600 Units (U) of Epogen (epoetin alfa) received per week at Baseline.
MK2578 1mcg/600U QM	MK2578 IV was administered QM. Participants were randomized to receive 1 mcg of MK2578 for every 600 U of Epogen (epoetin alpha) received per week at Baseline.
MK2578 1mcg/350U QW	MK2578 IV was administered QW. Participants were randomized to receive 1 mcg of MK2578 for every 350 U of Epogen (epoetin alpha) received per week at Baseline.
MK2578 1mcg/350U QM	MK2578 IV was administered QM. Participants were randomized to receive 1 mcg of MK2578 for every 350 U of Epogen (epoetin alpha) received per week at Baseline.

Measured Values

	MK2578 1mcg/600U QW	**MK2578 1mcg/600U QM**	**MK2578 1mcg/350U QW**	**MK2578 1mcg/350U QM**
Number of Participants Analyzed [units: participants]	**16**	**14**	**1**	**1**
Change From Baseline in Hemoglobin (Hg) Level at Week 4 [units: g/dL] Mean (Standard Deviation)	**-0.6 (0.8)**	**-0.7 (1.0)**	**-1.0** [1]	**-1.0** [1]

[1] Only one patient was included in this analysis, thus the SD is not calculated.

No statistical analysis provided for Change From Baseline in Hemoglobin (Hg) Level at Week 4

2. Primary: Number of Participants With Composite Events of Death, Myocardial Infarction (MI), and Cerebrovascular Accident (CVA) [Time Frame: 12 weeks]

Measure Type	Primary
Measure Title	Number of Participants With Composite Events of Death, Myocardial Infarction (MI), and Cerebrovascular Accident (CVA)
Measure Description	No text entered.
Time Frame	12 weeks
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.
No text entered.

Reporting Groups

	Description
MK2578 1mcg/600U QW	MK2578 IV was administered QW. Participants were randomized to receive 1 mcg of MK2578 for every 600 U of Epogen (epoetin alpha) received per week at Baseline.
MK2578 1mcg/600U QM	MK2578 IV was administered QM. Participants were randomized to receive 1 mcg of MK2578 for every 600 U of Epogen (epoetin alpha) received per week at Baseline.
MK2578 1mcg/350U QW	MK2578 IV was administered QW. Participants were randomized to receive 1 mcg of MK2578 for every 350 U of Epogen (epoetin alpha) received per week at Baseline.
MK2578 1mcg/350U QM	MK2578 IV was administered QM. Participants were randomized to receive 1 mcg of MK2578 for every 350 U of Epogen (epoetin alpha) received per week at Baseline.

Measured Values

	MK2578 1mcg/600U QW	**MK2578 1mcg/600U QM**	**MK2578 1mcg/350U QW**	**MK2578 1mcg/350U QM**
Number of Participants Analyzed [units: participants]	**16**	**15**	**4**	**4**
Number of Participants With Composite Events of Death, Myocardial Infarction (MI), and Cerebrovascular Accident (CVA) [units: Participants]	**0**	**1**	**0**	**0**

No statistical analysis provided for Number of Participants With Composite Events of Death, Myocardial Infarction (MI), and Cerebrovascular Accident (CVA)

3. Primary: Number of Participants With Composite Events of Transfusion-Related Adverse Experiences [Time Frame: 12 weeks]

Measure Type	Primary
Measure Title	Number of Participants With Composite Events of Transfusion-Related Adverse Experiences
Measure Description	No text entered.

Time Frame	12 weeks
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.
No text entered.

Reporting Groups

	Description
MK2578 1mcg/600U QW	MK2578 IV was administered QW. Participants were randomized to receive 1 mcg of MK2578 for every 600 U of Epogen (epoetin alpha) received per week at Baseline.
MK2578 1mcg/600U QM	MK2578 IV was administered QM. Participants were randomized to receive 1 mcg of MK2578 for every 600 U of Epogen (epoetin alpha) received per week at Baseline.
MK2578 1mcg/350U QW	MK2578 IV was administered QW. Participants were randomized to receive 1 mcg of MK2578 for every 350 U of Epogen (epoetin alpha) received per week at Baseline.
MK2578 1mcg/350U QM	MK2578 IV was administered QM. Participants were randomized to receive 1 mcg of MK2578 for every 350 U of Epogen (epoetin alpha) received per week at Baseline.

Measured Values

	MK2578 1mcg/600U QW	**MK2578 1mcg/600U QM**	**MK2578 1mcg/350U QW**	**MK2578 1mcg/350U QM**
Number of Participants Analyzed [units: participants]	**16**	**15**	**4**	**4**
Number of Participants With Composite Events of Transfusion-Related Adverse Experiences [units: Participants]	**0**	**0**	**0**	**0**

No statistical analysis provided for Number of Participants With Composite Events of Transfusion-Related Adverse Experiences

4. Primary: Number of Participants With Composite Events of Infusion Reactions [Time Frame: 12 weeks]

Measure Type	Primary
Measure Title	Number of Participants With Composite Events of Infusion Reactions
Measure Description	No text entered.
Time Frame	12 weeks
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.
No text entered.

Reporting Groups

	Description
MK2578 1mcg/600U QW	MK2578 IV was administered QW. Participants were randomized to receive 1 mcg of MK2578 for every 600 U of Epogen (epoetin alpha) received per week at Baseline.
MK2578 1mcg/600 QM	MK2578 IV was administered QM. Participants were randomized to receive 1 mcg of MK2578 for every 600 U of Epogen (epoetin alpha) received per week at Baseline.
MK2578 1mcg/350U QW	MK2578 IV was administered QW. Participants were randomized to receive 1 mcg of MK2578 for every 350 U of Epogen (epoetin alpha) received per week at Baseline.
MK2578 1mcg/350U QM	MK2578 IV was administered QM.Participants were randomized to receive 1 mcg of MK2578 for every 350 U of Epogen (epoetin alpha) received per week at Baseline.

Measured Values

	MK2578 1mcg/600U QW	MK2578 1mcg/600 QM	MK2578 1mcg/350U QW	MK2578 1mcg/350U QM
Number of Participants Analyzed [units: participants]	**16**	**15**	**4**	**4**
Number of Participants With Composite Events of Infusion Reactions [units: Participants]	**0**	**0**	**0**	**0**

No statistical analysis provided for Number of Participants With Composite Events of Infusion Reactions

5. Primary: Number of Participants With Events of Death, MI, CVA, Peripheral Vascular Thromboses, Vascular Access Thrombosis, Congestive Heart Failure (CHF), Hypertension, Seizure, or Pure Red Cell Aplasia [Time Frame: 12 weeks]

Measure Type	Primary
Measure Title	Number of Participants With Events of Death, MI, CVA, Peripheral Vascular Thromboses, Vascular Access Thrombosis, Congestive Heart Failure (CHF), Hypertension, Seizure, or Pure Red Cell Aplasia
Measure Description	No text entered.
Time Frame	12 weeks
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.
No text entered.

Reporting Groups

	Description
MK2578 1mcg/600U QW	MK2578 IV was administered QW. Participants were randomized to receive 1 mcg of MK2578 for every 600 U of Epogen (epoetin alpha) received per week at Baseline.
MK2578 1mcg/600U QM	MK2578 IV was administered QM. Participants were randomized to receive 1 mcg of MK2578 for every 600 U of Epogen (epoetin alpha) received per week at Baseline.
MK2578 1mcg/350U QW	MK2578 IV was administered QW. Participants were randomized to receive 1 mcg of MK2578 for every U of Epogen (epoetin alpha) received per week at Baseline.
MK2578 1mcg/350U QM	MK2578 IV was administered QM. Participants were randomized to receive 1 mcg of MK2578 for every 350 U of Epogen (epoetin alpha) received per week at Baseline.

Measured Values

	MK2578 1mcg/600U QW	MK2578 1mcg/600U QM	MK2578 1mcg/350U QW	MK2578 1mcg/350U QM
Number of Participants Analyzed [units: participants]	**16**	**15**	**4**	**4**
Number of Participants With Events of Death, MI, CVA, Peripheral Vascular Thromboses, Vascular Access Thrombosis, Congestive Heart Failure (CHF), Hypertension, Seizure, or Pure Red Cell Aplasia [units: Participants]				
Death	**0**	**0**	**0**	**0**
MI	**0**	**1**	**0**	**0**
CVA	**0**	**0**	**0**	**0**
Peripheral vascular thromboses	**0**	**0**	**0**	**0**
Vascular access thrombosis	**0**	**0**	**1**	**0**
CHF	**0**	**0**	**0**	**0**
Hypertension	**1**	**1**	**0**	**0**
Seizure	**0**	**0**	**0**	**0**
Pure red cell aplasia	**0**	**0**	**0**	**0**

No statistical analysis provided for Number of Participants With Events of Death, MI, CVA, Peripheral Vascular Thromboses, Vascular Access Thrombosis, Congestive Heart Failure (CHF), Hypertension, Seizure, or Pure Red Cell Aplasia

6. Primary: Number of Participants With Confirmed, Treatment Emergent Antibodies to MK2578 [Time Frame: 12 weeks]

Measure Type	Primary
Measure Title	Number of Participants With Confirmed, Treatment Emergent Antibodies to MK2578
Measure Description	No text entered.
Time Frame	12 weeks
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.
Immunogenicity assays for antibodies to MK2578 were not performed due to early study termination.

Reporting Groups

	Description
MK2578 1mcg/600U QW	MK2578 IV was administered QW. Participants were randomized to receive 1 mcg of MK2578 for every 600 U of Epogen (epoetin alpha) received per week at Baseline.
MK2578 1mcg/600U QM	MK2578 IV was administered QM. Participants were randomized to receive 1 mcg of MK2578 for every 600 U of Epogen (epoetin alpha) received per week at Baseline.
MK2578 1mcg/350U QW	MK2578 IV was administered QW. Participants were randomized to receive 1 mcg of MK2578 for every 350 U of

	Epogen (epoetin alpha) received per week at Baseline.
MK2578 1mcg/350U QM	MK2578 IV was administered QM. Participants were randomized to receive 1 mcg of MK2578 for every 350 U of Epogen (epoetin alpha) received per week at Baseline.

Measured Values

	MK2578 1mcg/600U QW	MK2578 1mcg/600U QM	MK2578 1mcg/350U QW	MK2578 1mcg/350U QM
Number of Participants Analyzed [units: participants]	**0**	**0**	**0**	**0**
Number of Participants With Confirmed, Treatment Emergent Antibodies to MK2578				

No statistical analysis provided for Number of Participants With Confirmed, Treatment Emergent Antibodies to MK2578

7. Secondary: Change From Baseline in Hg Level at Week 12 [Time Frame: 12 weeks]

Measure Type	Secondary
Measure Title	Change From Baseline in Hg Level at Week 12
Measure Description	No text entered.
Time Frame	12 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.
Full analysis set; due to study termination participants in the MK2578 1mcg/350U QW and MK2578 1mcg/350U QM were not analyzed.

Reporting Groups

	Description
MK2578 1mcg/600U QW	MK3578 IV was administered QW. Participants were randomized to receive 1 mcg of MK-2578 for every 600 U of Epogen (epoetin alpha) received per week at Baseline.
MK2578 1mcg/600U QM	MK2578 IV was administered QM. Participants were randomized to receive 1 mcg of MK2578 for every 600 Units (U) of Epogen (epoetin alfa) received per week at Baseline.
MK2578 1mcg/350U QW	MK2578 IV was administered QW. Participants were randomized to receive 1 mcg of MK2578 for every 350 Units (U) of Epogen (epoetin alfa) received per week at Baseline.
MK-2578 1mcg/350U QM	MK2578 IV was administered QM. Participatns were randomized to receive 1 mcg of MK2578 for every 350 Units (U) of Epogen (epoetin alpha) received per 4 weeks at Baseline.

Measured Values

	MK2578 1mcg/600U QW	MK2578 1mcg/600U QM	MK2578 1mcg/350U QW	MK-2578 1mcg/350U QM
Number of Participants Analyzed [units: participants]	**6**	**11**	**0**	**0**
Change From Baseline in Hg Level at Week 12 [units: g/dL]	**-0.1 (1.4)**	**-0.5 (1.4)**		

Mean (Standard Deviation)				

No statistical analysis provided for Change From Baseline in Hg Level at Week 12

Serious Adverse Events

Hide Serious Adverse Events

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

Reporting Groups

	Description
MK2578 QW	MK2578 IV administered once weekly.
MK2578 QM	MK2578 IV administered once every 4 weeks.

Serious Adverse Events

	MK2578 QW	MK2578 QM
Total, serious adverse events		
# participants affected / at risk	**1/20 (5.00%)**	**2/19 (10.53%)**
Cardiac disorders		
Acute mycoardial infarction [1]		
# participants affected / at risk	**0/20 (0.00%)**	**1/19 (5.26%)**
# events	**0**	**1**
Injury, poisoning and procedural complications		
Complications of transplanted kidney [1]		
# participants affected / at risk	**0/20 (0.00%)**	**1/19 (5.26%)**
# events	**0**	**1**
Respiratory, thoracic and mediastinal disorders		
Acute respiratory failure [1]		
# participants affected / at risk	**0/20 (0.00%)**	**1/19 (5.26%)**
# events	**0**	**1**
Pleural effusion [1]		
# participants affected / at risk	**1/20 (5.00%)**	**0/19 (0.00%)**
# events	**1**	**0**

1 Term from vocabulary, MedDRA 11.1

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	0%

Reporting Groups

	Description
MK2578 QW	MK2578 IV administered once weekly.
MK2578 QM	MK2578 IV administered once every 4 weeks.

Other Adverse Events

	MK2578 QW	MK2578 QM
Total, other (not including serious) adverse events		
# participants affected / at risk	**9/20 (45.00%)**	**7/19 (36.84%)**
Cardiac disorders		
Acute myocardial infarction [1]		
# participants affected / at risk	**0/20 (0.00%)**	**1/19 (5.26%)**
# events	**0**	**1**
Atrial fibrillation [1]		
# participants affected / at risk	**1/20 (5.00%)**	**0/19 (0.00%)**
# events	**1**	**0**
Tachycardia [1]		
# participants affected / at risk	**1/20 (5.00%)**	**0/19 (0.00%)**
# events	**1**	**0**
Endocrine disorders		
Adrenal cyst [1]		
# participants affected / at risk	**0/20 (0.00%)**	**1/19 (5.26%)**
# events	**0**	**1**
Gastrointestinal disorders		
Abdominal distention [1]		
# participants affected / at risk	**0/20 (0.00%)**	**1/19 (5.26%)**
# events	**0**	**1**
Gastritis [1]		
# participants affected / at risk	**0/20 (0.00%)**	**1/19 (5.26%)**
# events	**0**	**1**
[1]		

Nausea		
# participants affected / at risk	**0/20 (0.00%)**	**1/19 (5.26%)**
# events	**0**	**1**
Oesophagitis [1]		
# participants affected / at risk	**0/20 (0.00%)**	**1/19 (5.26%)**
# events	**0**	**1**
General disorders		
Asthenia [1]		
# participants affected / at risk	**0/20 (0.00%)**	**1/19 (5.26%)**
# events	**0**	**1**
Non-cardiac chest pain [1]		
# participants affected / at risk	**0/20 (0.00%)**	**1/19 (5.26%)**
# events	**0**	**1**
Oedema peripheral [1]		
# participants affected / at risk	**0/20 (0.00%)**	**1/19 (5.26%)**
# events	**0**	**1**
Infections and infestations		
Bacterial disease carrier [1]		
# participants affected / at risk	**0/20 (0.00%)**	**1/19 (5.26%)**
# events	**0**	**1**
Bronchitis [1]		
# participants affected / at risk	**0/20 (0.00%)**	**1/19 (5.26%)**
# events	**0**	**1**
Gastroenteritis viral [1]		
# participants affected / at risk	**1/20 (5.00%)**	**0/19 (0.00%)**
# events	**1**	**0**
Pneumonia [1]		
# participants affected / at risk	**0/20 (0.00%)**	**1/19 (5.26%)**
# events	**0**	**1**
Injury, poisoning and procedural complications		
Accidental overdose [1]		
# participants affected / at risk	**0/20 (0.00%)**	**1/19 (5.26%)**
# events	**0**	**1**
Arteriovenous fistula site complication [1]		
# participants affected / at risk	**1/20 (5.00%)**	**0/19 (0.00%)**
# events	**1**	**0**
Arteriovenous fistula thrombosis [1]		
# participants affected / at risk	**1/20 (5.00%)**	**0/19 (0.00%)**
# events	**1**	**0**
Complications of transplanted kidney [1]		
# participants affected / at risk	**0/20 (0.00%)**	**1/19 (5.26%)**
# events	**0**	**1**
Haemodialysis-induced symptom [1]		
# participants affected / at risk	**0/20 (0.00%)**	**1/19 (5.26%)**
# events	**0**	**1**

Procedural hypertension [1]		
# participants affected / at risk	**1/20 (5.00%)**	**0/19 (0.00%)**
# events	**1**	**0**
Procedural hypotension [1]		
# participants affected / at risk	**0/20 (0.00%)**	**1/19 (5.26%)**
# events	**0**	**1**
Investigations		
Blood pressure increased [1]		
# participants affected / at risk	**0/20 (0.00%)**	**1/19 (5.26%)**
# events	**0**	**1**
Haemoglobin decreased [1]		
# participants affected / at risk	**0/20 (0.00%)**	**1/19 (5.26%)**
# events	**0**	**1**
Ultrasound pelvis abnormal [1]		
# participants affected / at risk	**0/20 (0.00%)**	**1/19 (5.26%)**
# events	**0**	**1**
Metabolism and nutrition disorders		
Decreased appetite [1]		
# participants affected / at risk	**0/20 (0.00%)**	**1/19 (5.26%)**
# events	**0**	**1**
Fluid retention [1]		
# participants affected / at risk	**0/20 (0.00%)**	**1/19 (5.26%)**
# events	**0**	**1**
Musculoskeletal and connective tissue disorders		
Back pain [1]		
# participants affected / at risk	**0/20 (0.00%)**	**1/19 (5.26%)**
# events	**0**	**1**
Muscle spasms [1]		
# participants affected / at risk	**1/20 (5.00%)**	**1/19 (5.26%)**
# events	**1**	**1**
Pain in extremity [1]		
# participants affected / at risk	**1/20 (5.00%)**	**0/19 (0.00%)**
# events	**1**	**0**
Spinal osteoarthritis [1]		
# participants affected / at risk	**0/20 (0.00%)**	**1/19 (5.26%)**
# events	**0**	**1**
Nervous system disorders		
Dizziness [1]		
# participants affected / at risk	**0/20 (0.00%)**	**1/19 (5.26%)**
# events	**0**	**1**
Headache [1]		
# participants affected / at risk	**1/20 (5.00%)**	**0/19 (0.00%)**
# events	**1**	**0**
Metabolic encephalopathy [1]		

# participants affected / at risk	0/20 (0.00%)	1/19 (5.26%)
# events	0	1
Vertebrobasilar insufficiency [1]		
# participants affected / at risk	0/20 (0.00%)	1/19 (5.26%)
# events	0	1
Psychiatric disorders		
Anxiety [1]		
# participants affected / at risk	0/20 (0.00%)	1/19 (5.26%)
# events	0	1
Renal and urinary disorders		
Renal vein thrombosis [1]		
# participants affected / at risk	0/20 (0.00%)	1/19 (5.26%)
# events	0	1
Reproductive system and breast disorders		
Menorrhagia [1]		
# participants affected / at risk	1/20 (5.00%)	0/19 (0.00%)
# events	1	0
Respiratory, thoracic and mediastinal disorders		
Acute respiratory failure [1]		
# participants affected / at risk	0/20 (0.00%)	1/19 (5.26%)
# events	0	1
Pleural effusion [1]		
# participants affected / at risk	1/20 (5.00%)	0/19 (0.00%)
# events	1	0
Skin and subcutaneous tissue disorders		
Skin discolouration [1]		
# participants affected / at risk	0/20 (0.00%)	1/19 (5.26%)
# events	0	1
Vascular disorders		
Arterial occlusive disease [1]		
# participants affected / at risk	1/20 (5.00%)	0/19 (0.00%)
# events	1	0
Brachiocephalic vein stenosis [1]		
# participants affected / at risk	1/20 (5.00%)	0/19 (0.00%)
# events	1	0
Hypertension [1]		
# participants affected / at risk	1/20 (5.00%)	0/19 (0.00%)
# events	1	0
Hypotension [1]		
# participants affected / at risk	0/20 (0.00%)	1/19 (5.26%)
# events	0	1

1 Term from vocabulary, MedDRA 11.1

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

Cohort 3 (MK2578 1mcg/200U) was not initiated because the study was prematurely

terminated by the sponsor. All randomized participants received at least one dose of study medication. Data presented are for Cohort 1 and Cohort 2, where applicable.

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: The sponsor must have the opportunity to review all proposed abstracts, manuscripts, or presentations regarding this study 60 days prior to submission for publication/presentation. Any information identified by the sponsor as confidential must be deleted prior to submission. Sponsor review can be expedited to meet publication guidelines.

Results Point of Contact:

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Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00924781 History of Changes
Other Study ID Numbers:	2578-003 2009_603
Study First Received:	June 18, 2009
Results First Received:	October 25, 2011
Last Updated:	October 30, 2015
Health Authority:	United States: Food and Drug Administration

TO TOP

For Patients and Families | For Researchers | For Study Record Managers

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