A Study of MK2578 in Patients With Chronic Kidney Disease Who Are Not on Dialysis (2578-002)

This study has been terminated.

Sponsor:
Merck Sharp & Dohme Corp.

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

ClinicalTrials.gov Identifier:
NCT00968617

First received: August 27, 2009
Last updated: October 30, 2015
Last verified: October 2015
History of Changes

Purpose

This study will define an effective starting dose for subcutaneous administration of MK2578 to correct anemia in erythropoiesis-stimulating agent (ESA)-naive patients with chronic kidney disease (CKD) who are not on dialysis while evaluating its safety.

Condition	Intervention	Phase
Anemia Chronic Kidney Disease	Drug: MK2578 Drug: Comparator: darbepoetin alfa	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 IIb Randomized, Active Comparator-Controlled, Open-Label Clinical Trial to Study the Efficacy and Safety of MK2578 for the Treatment of Anemia in ESA (Erythropoiesis-Stimulating Agent)-Naive Patients With Chronic Kidney Disease Who Are Not on Dialysis.

Resource links provided by NLM:

MedlinePlus related topics: Anemia Kidney Diseases

Drug Information available for: Darbepoetin Alfa

U.S. FDA Resources

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

Primary Outcome Measures:

- Change From Baseline in Hemoglobin Level at Week 4 [Time Frame: 4 weeks] [Designated as safety issue: No]
- Number of Participants With Composite Events of Death, Myocardial Infarction and Cerebrovascular Accident, Serious Events of Unstable Angina, Transient Ischemic Attack, Arrythmia and Congestive Heart Failure, Peripheral Thrombo-embolic Events [Time Frame: 16 Weeks] [Designated as safety issue: Yes]
- Number of Participants With Composite Events of Transfusion-related Adverse Experiences [Time Frame: 16 Weeks] [Designated as safety issue: Yes]
- Number of of Participants With Composite Events of Injection Site Reactions [Time Frame: 16 Weeks] [Designated as safety issue: Yes]
- Number of Participants With Hypertension, Seizure, and Pure Red Cell Aplasia [Time Frame: 16 Weeks] [Designated as safety issue: Yes]
- Number of Participants With Confirmed, Treatment Emergent Antibodies to MK2578 [Time Frame: 16 Weeks] [Designated as safety issue: Yes]

Secondary Outcome Measures:

- Hemoglobin Concentration After Treatment With MK2578 [Time Frame: Weeks 1-10 and Week 12] [Designated as safety issue: No]
- Change From Baseline in Hemoglobin Level [Time Frame: Weeks 1-3, 5-10, and Week 12] [Designated as safety issue: No]
- Number of Participants Who Were Responders [Time Frame: Each week up to 12 weeks] [Designated as safety issue: No]

  Responder was defined as a participant achieving (pre-transfusion) an increase from baseline hemoglobin of greater than or equal to 1 g/dL and a hemoglobin concentration of greater than or equal to 11 g/dL.

Enrollment:	7
Study Start Date:	November 2009
Study Completion Date:	May 2010
Primary Completion Date:	April 2010 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: MK2578 1.0 mcg/kg MK2578	Drug: MK2578 MK2578 1.0 mcg/kg/month
Experimental: MK2578 2.0 mcg/kg MK2578	Drug: MK2578 MK2578 2.0 mcg/kg/month
Experimental: MK2578 3.6 mcg/kg MK2578	Drug: MK2578 MK2578 3.6 mcg/kg/month
Active Comparator: Darbepoetin alfa darbepoetin alfa	Drug: Comparator: darbepoetin alfa darbepoetin alfa

Eligibility

Ages Eligible for Study:	18 Years to 75 Years (Adult, Senior)
Genders Eligible for Study:	Both
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- Patient is male or is a female who either cannot have children or who agrees to use appropriate contraceptive measures
- Patient has chronic kidney disease

Exclusion Criteria:

- Patient is morbidly obese
- Patient has used another erythropoiesis (red blood cell formation) stimulating agent within 12 weeks of screening
- Patient will require dialysis during the study or is planning to have 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 the past 12 weeks or plans to have surgery

- Patient has Human Immunodeficiency Virus (HIV)
- Patient has a history of diseases other than CKD known to cause anemia
- Patient has severe congestive heart failure
- Patient has history of malignant cancer, except certain skin or cervical cancers
- Patient has a history of grand mal seizures within the last 6 months
- Patient is pregnant or breastfeeding

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: NCT00968617

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:	NCT00968617 History of Changes
Other Study ID Numbers:	**2578-002** 2009_653
Study First Received:	August 27, 2009
Results First Received:	October 7, 2011
Last Updated:	October 30, 2015
Health Authority:	United States: Food and Drug Administration

Keywords provided by Merck Sharp & Dohme Corp.:
Anemia

Additional relevant MeSH terms:

Anemia	Urologic Diseases
Kidney Diseases	Renal Insufficiency
Renal Insufficiency, Chronic	Hematinics
Hematologic Diseases	Darbepoetin alfa

ClinicalTrials.gov processed this record on December 01, 2016

TO TOP

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

HOME RSS FEEDS SITE MAP TERMS AND CONDITIONS DISCLAIMER CONTACT NLM HELP DESK

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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 7, 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 Drug: Comparator: darbepoetin 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
Participants in Cohorts 1 and 2 were to receive 1.0 mcg/kg/month and 2.0 mcg/kg/month, respectively, of MK2578. Participants in Cohort 3 were to be randomized to MK2578 3.6 mcg/kg/month or to weekly doses of darbepoetin alfa 0.45 mcg/kg/week. Cohort 1 was the only cohort initiated.

Reporting Groups

	Description
MK2578	MK2578 1.0 mcg/kg given subcutaneously (SC) every month.

Participant Flow: Overall Study

	MK2578
STARTED	**7**
COMPLETED	**1**
NOT COMPLETED	**6**
Study terminated by sponsor	**6**

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	MK2578 1.0 mcg/kg given subcutaneously (SC) every month.

Baseline Measures

	MK2578
Overall Participants Analyzed [Units: Participants]	**7**
Age [Units: Years] Mean (Standard Deviation)	**60.9 (5.01)**
Gender [Units: Participants]	
Female	**3**
Male	**4**

Outcome Measures

Hide All Outcome Measures

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

Measure Type	Primary

Measure Title	Change From Baseline in Hemoglobin 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.
No text entered.

Reporting Groups

	Description
MK2578	MK2578 1.0 mcg/kg given subcutaneously (SC) every month.

Measured Values

	MK2578
Participants Analyzed [Units: Participants]	**7**
Change From Baseline in Hemoglobin Level at Week 4 [Units: g/dL] Mean (Standard Deviation)	
Baseline Hemoglobin	**9.3 (0.4)**
Change from Baseline in Hemoglobin at Week 4	**0.5 (0.4)**

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

2. Primary: Number of Participants With Composite Events of Death, Myocardial Infarction and Cerebrovascular Accident, Serious Events of Unstable Angina, Transient Ischemic Attack, Arrythmia and Congestive Heart Failure, Peripheral Thrombo-embolic Events [Time Frame: 16 Weeks]

Measure Type	Primary
Measure Title	Number of Participants With Composite Events of Death, Myocardial Infarction and Cerebrovascular Accident, Serious Events of Unstable Angina, Transient Ischemic Attack, Arrythmia and Congestive Heart Failure, Peripheral Thrombo-embolic Events
Measure Description	No text entered.
Time Frame	16 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	MK2578 1.0 mcg/kg given subcutaneously (SC) every month.

Measured Values

	MK2578
Participants Analyzed [Units: Participants]	**7**
Number of Participants With Composite Events of Death, Myocardial Infarction and Cerebrovascular Accident, Serious Events of Unstable Angina, Transient Ischemic Attack, Arrythmia and Congestive Heart Failure, Peripheral Thrombo-embolic Events [Units: Participants]	**0**

No statistical analysis provided for Number of Participants With Composite Events of Death, Myocardial Infarction and Cerebrovascular Accident, Serious Events of Unstable Angina, Transient Ischemic Attack, Arrythmia and Congestive Heart Failure, Peripheral Thrombo-embolic Events

3. Primary: Number of Participants With Composite Events of Transfusion-related Adverse Experiences [Time Frame: 16 Weeks]

Measure Type	Primary
Measure Title	Number of Participants With Composite Events of Transfusion-related Adverse Experiences
Measure Description	No text entered.
Time Frame	16 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	MK2578 1.0 mcg/kg given subcutaneously (SC) every month.

Measured Values

	MK2578
Participants Analyzed [Units: Participants]	**7**
Number of Participants With Composite Events of Transfusion-related Adverse Experiences [Units: Participants]	**0**

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

4. Primary: Number of of Participants With Composite Events of Injection Site Reactions [Time Frame: 16 Weeks]

Measure Type	Primary
Measure Title	Number of of Participants With Composite Events of Injection Site Reactions
Measure Description	No text entered.
Time Frame	16 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	MK2578 1.0 mcg/kg given subcutaneously (SC) every month.

Measured Values

	MK2578
Participants Analyzed [Units: Participants]	**7**
Number of of Participants With Composite Events of Injection Site Reactions [Units: Participants]	**1**

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

5. Primary: Number of Participants With Hypertension, Seizure, and Pure Red Cell Aplasia [Time Frame: 16 Weeks]

Measure Type	Primary
Measure Title	Number of Participants With Hypertension, Seizure, and Pure Red Cell Aplasia
Measure Description	No text entered.
Time Frame	16 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	MK2578 1.0 mcg/kg given subcutaneously (SC) every month.

Measured Values

	MK2578
Participants Analyzed [Units: Participants]	**7**
Number of Participants With Hypertension, Seizure, and Pure Red Cell Aplasia [Units: Participants]	
Hypertension	**1**
Seizure	**0**
Pure red cell aplasia	**0**

No statistical analysis provided for Number of Participants With Hypertension, Seizure, and Pure Red Cell Aplasia

6. Primary: Number of Participants With Confirmed, Treatment Emergent Antibodies to MK2578 [Time Frame: 16 Weeks]

Measure Type	Primary
Measure Title	Number of Participants With Confirmed, Treatment Emergent Antibodies to MK2578
Measure Description	No text entered.
Time Frame	16 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	MK2578 1.0 mcg/kg given subcutaneously (SC) every month.

Measured Values

	MK2578
Participants Analyzed [Units: Participants]	**7**
Number of Participants With Confirmed, Treatment Emergent Antibodies to MK2578 [Units: Participants]	**NA** [1]

[1] Immunogenicity assays for antibodies to MK2578 were not performed due to early study termination.

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

7. Secondary: Hemoglobin Concentration After Treatment With MK2578 [Time Frame: Weeks 1-10 and Week 12]

Measure Type	Secondary
Measure Title	Hemoglobin Concentration After Treatment With MK2578
Measure Description	No text entered.
Time Frame	Weeks 1-10 and Week 12
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.
No text entered.

Reporting Groups

	Description
MK2578	MK2578 1.0 mcg/kg given subcutaneously (SC) every month.

Measured Values

	MK2578
Participants Analyzed [Units: Participants]	**7**
Hemoglobin Concentration After Treatment With MK2578 [Units: g/dL] Mean (Standard Deviation)	
Week 1 (n=6)	**9.2 (0.8)**
Week 2 (n=5)	**9.8 (0.6)**
Week 3 (n=5)	**9.9 (0.7)**
Week 4 (n=7)	**9.8 (0.6)**
Week 5 (n=5)	**10.3 (0.7)**
Week 6 (n=4)	**10.4 (0.8)**
Week 7 (n=3)	**10.8 (0.9)**
Week 8 (n=4)	**11.1 (0.7)**
Week 9 (n=2)	**10.9 (0.4)**
Week 10 (n=1)	**10.6** [1]
Week 12 (n=1)	**11.1** [1]

[1] No standard deviation exists for n=1.

No statistical analysis provided for Hemoglobin Concentration After Treatment With MK2578

8. Secondary: Change From Baseline in Hemoglobin Level [Time Frame: Weeks 1-3, 5-10, and Week 12]

Measure Type	Secondary
Measure Title	Change From Baseline in Hemoglobin Level
Measure Description	No text entered.
Time Frame	Weeks 1-3, 5-10, and Week 12
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.
No text entered.

Reporting Groups

	Description
MK2578	MK2578 1.0 mcg/kg given subcutaneously (SC) every month.

Measured Values

	MK2578
Participants Analyzed [Units: Participants]	**7**
Change From Baseline in Hemoglobin Level [Units: g/dL] Mean (Standard Deviation)	
Change from Baseline in Hemoglobin at Week 1 (n=6)	**-0.1 (0.6)**
Change from Baseline in Hemoglobin at Week 2 (n=5)	**0.5 (0.4)**
Change from Baseline in Hemoglobin at Week 3 (n=5)	**0.6 (0.7)**
Change from Baseline in Hemoglobin at Week 5 (n=5)	**0.9 (0.4)**
Change from Baseline in Hemoglobin at Week 6 (n=4)	**1.0 (0.6)**
Change from Baseline in Hemoglobin at Week 7 (n=3)	**1.3 (0.7)**
Change from Baseline in Hemoglobin at Week 8 (n=4)	**1.6 (0.4)**
Change from Baseline in Hemoglobin at Week 9 (n=2)	**1.5 (0.1)**
Change from Baseline in Hemoglobin at Week 10(n=1)	**1.6** [1]
Change from Baseline in Hemoglobin at Week 12(n=1)	**2.1** [1]

[1] No standard deviation exists for n=1.

No statistical analysis provided for Change From Baseline in Hemoglobin Level

9. Secondary: Number of Participants Who Were Responders [Time Frame: Each week up to 12 weeks]

Measure Type	Secondary
Measure Title	Number of Participants Who Were Responders
Measure Description	Responder was defined as a participant achieving (pre-transfusion) an increase from baseline hemoglobin of greater than or equal to 1 g/dL and a hemoglobin concentration of greater than or equal to 11 g/dL.

Time Frame	Each week up to 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.
No text entered.

Reporting Groups

	Description
MK2578	MK2578 1.0 mcg/kg given subcutaneously (SC) every month.

Measured Values

	MK2578
Participants Analyzed [Units: Participants]	**7**
Number of Participants Who Were Responders [Units: Participants]	**4**

No statistical analysis provided for Number of Participants Who Were Responders

Serious Adverse Events

Hide Serious Adverse Events

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

Reporting Groups

	Description
MK-2578	No text entered.

Serious Adverse Events

	MK-2578
Total, serious adverse events	
# participants affected / at risk	**0/7 (0.00%)**

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
MK-2578	No text entered.

Other Adverse Events

	MK-2578
Total, other (not including serious) adverse events	
# participants affected / at risk	**4/7 (57.14%)**
Cardiac disorders	
Tachycardia † 1	
# participants affected / at risk	**1/7 (14.29%)**
# events	**1**
Eye disorders	
Retinal detachment † 1	
# participants affected / at risk	**1/7 (14.29%)**
# events	**1**
Gastrointestinal disorders	
Vomiting † 1	
# participants affected / at risk	**1/7 (14.29%)**
# events	**1**
Infections and infestations	
Urinary tract infection † 1	
# participants affected / at risk	**1/7 (14.29%)**
# events	**1**
Injury, poisoning and procedural complications	
Accidental overdose † 1	
# participants affected / at risk	**1/7 (14.29%)**
# events	**1**
Contusion † 1	
# participants affected / at risk	**1/7 (14.29%)**
# events	**1**
Vascular disorders	
Hypertension † 1	

# participants affected / at risk	1/7 (14.29%)
# events	1

† Events were collected by systematic assessment
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 1 (MK2578 1.0 mcg/kg) was the only cohort initiated because the study was prematurely terminated by the sponsor. 7 participants received at least 1 dose of MK2578 & 2 participants received all 3 doses. Data presented are for Cohort 1.

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:

Name/Title: Senior Vice President, Global Clinical Development
Organization: Merck, Sharp & Dohme Corp.
e-mail: ClinicalTrialsDisclosure@merck.com

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TO TOP

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

HOME RSS FEEDS SITE MAP TERMS AND CONDITIONS DISCLAIMER CONTACT NLM HELP DESK