A Study to Assess the Safety and Efficacy of MK8245 in Patients With Type 2 Diabetes Mellitus and Inadequate Glycemic Control (MK8245-005 AM2)

This study has been terminated.

(Study was terminated due to inability to recruit patients.)

Sponsor:
Merck Sharp & Dohme Corp.

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

ClinicalTrials.gov Identifier:
NCT00846391

First received: February 17, 2009
Last updated: February 4, 2016
Last verified: February 2016
History of Changes

Purpose

A study to assess the safety and efficacy of MK8245 as monotherapy compared to placebo.

Condition	Intervention	Phase
Type 2 Diabetes Mellitus	Drug: MK8245 5 mg (twice a day) b.i.d. Drug: MK8245 50 mg b.i.d. Drug: Placebo	Phase 2

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Safety/Efficacy Study
Intervention Model: Parallel Assignment
Masking: Double Blind (Subject, Investigator)
Primary Purpose: Treatment

Official Title: A Phase IIa, Multicenter, Double-Blind, Placebo-Controlled Clinical Trial to Study the Efficacy and Safety of MK8245 in Patients With Type 2 Diabetes Mellitus With Inadequate Glycemic Control

Resource links provided by NLM:

MedlinePlus related topics: Diabetes Type 2

U.S. FDA Resources

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

Primary Outcome Measures:

Change From Baseline in 24-hour Weighted Mean Glucose (WMG) at Week 4 [Time Frame: Baseline and Week 4]
[Designated as safety issue: No]

The 24-hour WMG is derived from multiple glucose values collected during both fasting and post-meal periods. A "weighted" rather than a "simple" mean is used to avoid overrepresentation of post-meal glucose values. Blood samples for glucose were to be collected immediately prior to (sample -10 minutes), and 0, 15, 30, 60, 90, 120, and 180 minutes after each meal, and overnight (at midnight, 3 AM, and 5 AM) and fasting at 7 AM. Patients were to be domiciled for approximately 26 hours at the site where standard meals were provided and physical activity monitored.

Enrollment:	14
Study Start Date:	December 2008
Study Completion Date:	August 2009
Primary Completion Date:	August 2009 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: MK8245 5 mg b.i.d. MK8245	Drug: MK8245 5 mg (twice a day) b.i.d. All patients will receive placebo capsules 2 weeks prior to treatment period to be taken twice daily. Patients randomized to the 5 mg b.i.d. treatment group took 2 capsules of MK8245 2.5 mg in the morning and 2 capsules of MK8245 2.5 mg in the evening. Other Name: MK8245
Experimental: MK8245 50 mg b.i.d. MK8245	Drug: MK8245 50 mg b.i.d. All patients will receive placebo capsules 2 weeks prior to treatment period to be taken twice daily. Patients randomized to the 50 mg b.i.d. treatment group took 2 capsules of MK8245 25 mg in the morning and 2 capsules of MK8245 25 mg in the evening. Other Name: MK8245
Placebo Comparator: Placebo Placebo	Drug: Placebo All patients will receive placebo capsules 2 weeks prior to treatment period to be taken twice daily. Patients randomized to the placebo treatment group took 2 capsules of placebo matching MK8245 capsules in the morning and 2 placebo capsules matching MK8245 capsules in the evening.

Eligibility

Ages Eligible for Study:	18 Years to 65 Years
Genders Eligible for Study:	Both
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- Have Type 2 Diabetes Mellitus
- 18 to 65 years of age

Exclusion Criteria:

- History of Type 1 Diabetes or ketoacidosis
- Have been treated with lipid lowering medications 4 weeks before starting the study
- Have started on a weight loss program and not in the maintenance phase or have started weight loss medication within the last 12 weeks
- Have had surgery in the last 30 days
- History of active liver disease
- History of coronary heart disease or congestive heart failure
- Have had a stroke or transient ischemic neurological disorder in the past 6 months
- Are Human Immunodeficiency Virus (HIV) Positive

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: NCT00846391

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:	NCT00846391 History of Changes
Other Study ID Numbers:	8245-005 2009_541
Study First Received:	February 17, 2009
Results First Received:	August 26, 2010
Last Updated:	February 4, 2016
Health Authority:	United States: Food and Drug Administration

Additional relevant MeSH terms:
Diabetes Mellitus
Diabetes Mellitus, Type 2
Endocrine System Diseases
Glucose Metabolism Disorders
Metabolic Diseases

ClinicalTrials.gov processed this record on May 08, 2016

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A Study to Assess the Safety and Efficacy of MK8245 in Patients With Type 2 Diabetes Mellitus and Inadequate Glycemic Control (MK8245-005 AM2)

This study has been terminated.

(Study was terminated due to inability to recruit patients.)

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Merck Sharp & Dohme Corp.

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

ClinicalTrials.gov Identifier:
NCT00846391

First received: February 17, 2009
Last updated: February 4, 2016
Last verified: February 2016
History of Changes

Results First Received: August 26, 2010

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Investigator); Primary Purpose: Treatment
Condition:	Type 2 Diabetes Mellitus
Interventions:	Drug: MK8245 5 mg (twice a day) b.i.d. Drug: MK8245 50 mg b.i.d. Drug: Placebo

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

First Patient In:10-Feb-2009

Early Termination*:11-Aug-2009

Last Patient Last Visit:19-Aug-2009

10 Centers Worldwide

*Study was terminated due to inability to recruit patients. Because it was not terminated for safety concerns, sites were to see patients for early termination visit at earliest convenience. The last patient was seen 19-Aug-2009.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
Patients 18-65 yrs not on antihyperglycemic agent (AHA) (A1C 7-10%),or single AHA (A1C 7-9.5%),or low dose dual AHA therapy (A1C 6.5-9.5%) with type 2 diabetes mellitus entered a 4-wk diet/exercise period (AHA wash-off if on AHA),after which,those with fasting glucose of 130-250 mg/dL were eligible for randomization (after a 2 wk pbo run-in period)

Reporting Groups

	Description
MK8245 5 mg b.i.d.	Patients randomized to the 5 mg (twice a day) b.i.d. treatment group took 2 capsules of MK8245 2.5 mg in the morning and 2 capsules of MK8245 2.5 mg in the evening.
MK8245 50 mg b.i.d.	Patients randomized to the 50 mg b.i.d. treatment group took 2 capsules of MK8245 25 mg in the morning and 2 capsules of MK8245 25 mg in the evening.
Placebo	Patients randomized to the placebo treatment group took 2 capsules of placebo matching MK8245 capsules in the morning and 2 placebo capsules matching MK8245 capsules in the evening.

Participant Flow: Overall Study

	MK8245 5 mg b.i.d.	MK8245 50 mg b.i.d.	Placebo
STARTED	4	4	6
COMPLETED	3	2	3
NOT COMPLETED	1	2	3
Physician Decision	0	0	1
Study Terminated by Sponsor	1	2	2

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
MK8245 5 mg b.i.d.	Patients randomized to the 5 mg (twice a day) b.i.d. treatment group took 2 capsules of MK8245 2.5 mg in the morning and 2 capsules of MK8245 2.5 mg in the evening.
MK8245 50 mg b.i.d.	Patients randomized to the 50 mg b.i.d. treatment group took 2 capsules of MK8245 25 mg in the morning and 2 capsules of MK8245 25 mg in the evening.
Placebo	Patients randomized to the placebo treatment group took 2 capsules of placebo matching MK8245 capsules in the morning and 2 placebo capsules matching MK8245 capsules in the evening.
Total	Total of all reporting groups

Baseline Measures

	MK8245 5 mg b.i.d.	MK8245 50 mg b.i.d.	Placebo	Total
Number of Participants [units: participants]	4	4	6	14
Age [units: years] Mean (Standard Deviation)	49.8 (13.4)	55.5 (7.7)	53.5 (7.5)	53.0 (9.0)
Gender [units: participants]				
Female	2	4	5	11
Male	2	0	1	3
Ethnicity (NIH/OMB) [units: participants]				
Hispanic or Latino	2	2	3	7
Not Hispanic or Latino	2	2	3	7
Unknown or Not Reported	0	0	0	0
Race/Ethnicity, Customized [units: participants]				
Black OR African American	0	0	1	1
Multi-Racial	1	0	0	1
White	3	4	5	12

Outcome Measures

1. Primary: Change From Baseline in 24-hour Weighted Mean Glucose (WMG) at Week 4 [Time Frame: Baseline and Week 4]

Hide Outcome Measure 1

Measure Type	Primary
Measure Title	Change From Baseline in 24-hour Weighted Mean Glucose (WMG) at Week 4
Measure Description	The 24-hour WMG is derived from multiple glucose values collected during both fasting and post-meal periods. A "weighted" rather than a "simple" mean is used to avoid overrepresentation of post-meal glucose values. Blood samples for glucose were to be collected immediately prior to (sample -10 minutes), and 0, 15, 30, 60, 90, 120, and 180 minutes after each meal, and overnight (at midnight, 3 AM, and 5 AM) and fasting at 7 AM. Patients were to be domiciled for approximately 26 hours at the site where standard meals were provided and physical activity monitored.
Time Frame	Baseline and Week 4
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The analysis population included all patients with a baseline value and Week 4 value for this outcome.

Reporting Groups

	Description

MK8245 5 mg b.i.d.	Patients randomized to the 5 mg (twice a day) b.i.d. treatment group took 2 capsules of MK8245 2.5 mg in the morning and 2 capsules of MK8245 2.5 mg in the evening.
MK8245 50 mg b.i.d.	Patients randomized to the 50 mg b.i.d. treatment group took 2 capsules of MK8245 25 mg in the morning and 2 capsules of MK8245 25 mg in the evening.
Placebo	Patients randomized to the placebo treatment group took 2 capsules of placebo matching MK8245 capsules in the morning and 2 placebo capsules matching MK8245 capsules in the evening.

Measured Values

	MK8245 5 mg b.i.d.	MK8245 50 mg b.i.d.	Placebo
Number of Participants Analyzed [units: participants]	**3**	**2**	**3**
Change From Baseline in 24-hour Weighted Mean Glucose (WMG) at Week 4 [units: mg/dL] Mean (Standard Deviation)	**-18.9 (22.1)**	**18.7 (6.7)**	**-12.6 (1.4)**

No statistical analysis provided for Change From Baseline in 24-hour Weighted Mean Glucose (WMG) at Week 4

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	Adverse experiences were collected from Visit 2 (Week -6) through Visit 6 (Week 4). Serious adverse experiences were collected for up to 14 days after the last dose of study medication.
Additional Description	No text entered.

Reporting Groups

	Description
MK8245 5 mg b.i.d.	Patients randomized to the 5 mg (twice a day) b.i.d. treatment group took 2 capsules of MK8245 2.5 mg in the morning and 2 capsules of MK8245 2.5 mg in the evening.
MK8245 50 mg b.i.d.	Patients randomized to the 50 mg b.i.d. treatment group took 2 capsules of MK8245 25 mg in the morning and 2 capsules of MK8245 25 mg in the evening.
Placebo	Patients randomized to the placebo treatment group took 2 capsules of placebo matching MK8245 capsules in the morning and 2 placebo capsules matching MK8245 capsules in the evening.

Serious Adverse Events

	MK8245 5 mg b.i.d.	MK8245 50 mg b.i.d.	Placebo
Total, serious adverse events			
# participants affected / at risk	**0/4 (0.00%)**	**0/4 (0.00%)**	**0/6 (0.00%)**

Other Adverse Events

Hide Other Adverse Events

Time Frame	Adverse experiences were collected from Visit 2 (Week -6) through Visit 6 (Week 4). Serious adverse experiences were collected for up to 14 days after the last dose of study medication.
Additional Description	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
MK8245 5 mg b.i.d.	Patients randomized to the 5 mg (twice a day) b.i.d. treatment group took 2 capsules of MK8245 2.5 mg in the morning and 2 capsules of MK8245 2.5 mg in the evening.
MK8245 50 mg b.i.d.	Patients randomized to the 50 mg b.i.d. treatment group took 2 capsules of MK8245 25 mg in the morning and 2 capsules of MK8245 25 mg in the evening.
Placebo	Patients randomized to the placebo treatment group took 2 capsules of placebo matching MK8245 capsules in the morning and 2 placebo capsules matching MK8245 capsules in the evening.

Other Adverse Events

	MK8245 5 mg b.i.d.	**MK8245 50 mg b.i.d.**	**Placebo**
Total, other (not including serious) adverse events			
# participants affected / at risk	**3/4 (75.00%)**	**1/4 (25.00%)**	**3/6 (50.00%)**
Eye disorders			
Punctate keratitis * 1			
# participants affected / at risk	**0/4 (0.00%)**	**0/4 (0.00%)**	**1/6 (16.67%)**
Infections and infestations			
Cellulitis * 1			
# participants affected / at risk	**1/4 (25.00%)**	**0/4 (0.00%)**	**0/6 (0.00%)**
Oral herpes * 1			
# participants affected / at risk	**2/4 (50.00%)**	**0/4 (0.00%)**	**0/6 (0.00%)**
Upper respiratory tract infection * 1			
# participants affected / at risk	**1/4 (25.00%)**	**0/4 (0.00%)**	**0/6 (0.00%)**
Urinary tract infection * 1			
# participants affected / at risk	**0/4 (0.00%)**	**0/4 (0.00%)**	**1/6 (16.67%)**
Injury, poisoning and procedural complications			
Foot fracture * 1			
# participants affected / at risk	**1/4 (25.00%)**	**0/4 (0.00%)**	**0/6 (0.00%)**
Nervous system disorders			
Headadache * 1			
# participants affected / at risk	**0/4 (0.00%)**	**0/4 (0.00%)**	**1/6 (16.67%)**
Respiratory, thoracic and mediastinal disorders			

Nasal congestion * 1			
# participants affected / at risk	**0/4 (0.00%)**	**1/4 (25.00%)**	**0/6 (0.00%)**

* 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

This study was terminated due to the continuing inability to recruit patients. No efficacy analysis was performed because of insufficient sample size for meaningful analysis due to early study termination and insufficient sample size.

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: Merck agreements may vary with individual investigators, but will not prohibit any investigator from publishing. Merck supports the publication of results from all centers of a multi-center trial but requests that reports based on single-site data not precede the primary publication of the entire clinical trial.

Results Point of Contact:

Name/Title: Senior Vice President, Global Clinical Development
Organization: Merck Sharp & Dohme Corp.
phone: 1-800-672-6372
e-mail: ClinicalTrialsDisclosure@merck.com

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