A Study to Test MK-0941 in Adults With Type 2 Diabetes Mellitus With Inadequate Glycemic Control on Insulin (MK-0941-018)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

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

ClinicalTrials.gov Identifier:
NCT00824616

First received: January 16, 2009
Last updated: July 21, 2015
Last verified: July 2015
History of Changes

Purpose

The purpose of this study is to test the effect MK-0941 as add-on therapy for adults taking insulin for Type 2 Diabetes.

Condition	Intervention	Phase
Type 2 Diabetes Mellitus	Drug: MK-0941 Drug: Placebo Drug: Insulin	Phase 2

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

Official Title: A Phase IIa, Multicenter, Randomized, Double-Blind, Placebo-Controlled Clinical Trial of MK-0941 in Patients With Type 2 Diabetes Mellitus With Inadequate Glycemic Control on Insulin

Resource links provided by NLM:

MedlinePlus related topics: Diabetes Type 2

Drug Information available for: Insulin Insulin human

U.S. FDA Resources

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

Primary Outcome Measures:

- Change From Baseline in Hemoglobin A1c (HbA1c) Level [Time Frame: Baseline (Day 1) and End of Treatment (Week 20)] [Designated as safety issue: No]

  HbA1c level is a blood test measurement of the amount (percent) of hemoglobin that is glycated (or has glucose on it). HbA1c level is related to the average blood glucose concentration over the previous 2-3 months, with a higher HbA1c level indicating a higher amount of average plasma glucose. A negative number for change from baseline in HbA1c level means a reduction in HbA1c level and indicates better control of average plasma glucose levels.

- Number of Participants Who Experienced One or More Episodes of Hypoglycemia (Symptomatic or Asymptomatic) [Time Frame: From first dose of study drug (Week 0) to last dose of study drug (Week 20)] [Designated as safety issue: Yes]

  Hypoglycemic episodes - with or without symptoms - are defined as a fingerstick glucose measurement of ≤70 mg/dL (3.9 mmol/L). Excludes data after initiation of glycemic rescue therapy.

Enrollment:	68
Study Start Date:	January 2009
Study Completion Date:	May 2010
Primary Completion Date:	May 2010 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Placebo Comparator: Placebo Participants receiving placebo tablets three times daily plus insulin injection once daily	Drug: Placebo Placebo tablets, taken 3 times daily. Drug: Insulin Insulin glargine (rDNA origin) injection solution for subcutaneous (SC) injection, taken once daily. Other Name: LANTUS®
Experimental: MK-0941 Participants receiving MK-0941 tablets three times daily plus insulin injection once daily	Drug: MK-0941 MK-0941 tablets 5 mg or 10 mg, taken 3 times daily, with increasing doses to maximally effective dose. Drug: Insulin Insulin glargine (rDNA origin) injection solution for subcutaneous (SC) injection, taken once daily. Other Name: LANTUS®

Eligibility

Ages Eligible for Study:	21 Years to 70 Years
Genders Eligible for Study:	Both
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- Participant has Type 2 Diabetes Mellitus

Exclusion Criteria:

- Participant has a history of Type 1 Diabetes Mellitus or ketoacidosis
- Participant is on a weight loss program and is not in the maintenance phase or is taking a weight loss medication
- Participant has had surgery within 30 days of starting the study or has planned major surgery

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: NCT00824616

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:	NCT00824616 History of Changes
Other Study ID Numbers:	0941-018 2009_516 MK-0941-018
Study First Received:	January 16, 2009
Results First Received:	July 17, 2012
Last Updated:	July 21, 2015
Health Authority:	United States: Food and Drug Administration

Additional relevant MeSH terms:

Diabetes Mellitus	Insulin
Diabetes Mellitus, Type 2	Insulin, Globin Zinc
Endocrine System Diseases	Hypoglycemic Agents
Glucose Metabolism Disorders	Pharmacologic Actions
Metabolic Diseases	Physiological Effects of Drugs

ClinicalTrials.gov processed this record on April 14, 2016

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Results First Received: July 17, 2012

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Investigator); Primary Purpose: Treatment
Condition:	Type 2 Diabetes Mellitus
Interventions:	Drug: MK-0941 Drug: Placebo Drug: Insulin

Participant Flow

Hide Participant Flow

Recruitment Details

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

Pre-Assignment Details

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

Reporting Groups

	Description
Placebo	Participants receiving Placebo tablets 3 times daily plus insulin injection once daily
MK-0941	Participants receiving MK-0941 tablets 3 times daily plus insulin injection once daily

Participant Flow: Overall Study

	Placebo	MK-0941
STARTED	**34**	**34**
COMPLETED	**28**	**27**
NOT COMPLETED	**6**	**7**
Adverse Event	**2**	**1**
Creatinine/Creatinine Clearance	**0**	**2**
Hyperglycemia	**1**	**1**
Lack of Efficacy	**2**	**1**
Lost to Follow-up	**0**	**1**
Withdrawal by Subject	**1**	**1**

Baseline Characteristics

Hide Baseline Characteristics

Population Description

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

Reporting Groups

	Description
Placebo	Participants receiving Placebo tablets 3 times daily plus insulin injection once daily
MK-0941	Participants receiving MK-0941 tablets 3 times daily plus insulin injection once daily
Total	Total of all reporting groups

Baseline Measures

	Placebo	MK-0941	Total
Number of Participants [units: participants]	**34**	**34**	**68**
Age [units: years]	**55.5 (8.8)**	**54.1 (10.2)**	**54.8 (9.5)**

Mean (Standard Deviation)			
Gender [units: participants]			
Female	**15**	**16**	**31**
Male	**19**	**18**	**37**

Outcome Measures

Hide All Outcome Measures

1. Primary: Change From Baseline in Hemoglobin A1c (HbA1c) Level [Time Frame: Baseline (Day 1) and End of Treatment (Week 20)]

Measure Type	Primary
Measure Title	Change From Baseline in Hemoglobin A1c (HbA1c) Level
Measure Description	HbA1c level is a blood test measurement of the amount (percent) of hemoglobin that is glycated (or has glucose on it). HbA1c level is related to the average blood glucose concentration over the previous 2-3 months, with a higher HbA1c level indicating a higher amount of average plasma glucose. A negative number for change from baseline in HbA1c level means a reduction in HbA1c level and indicates better control of average plasma glucose levels.
Time Frame	Baseline (Day 1) and End of Treatment (Week 20)
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 Population, which consisted of all randomized participants who took at least one dose of study drug (MK-0941 or Placebo) and had a baseline or post-randomization measurement.

Reporting Groups

	Description
Placebo	Participants receiving Placebo tablets 3 times daily plus insulin injection once daily
MK-0941	Participants receiving MK-0941 tablets 3 times daily plus insulin injection once daily

Measured Values

	Placebo	**MK-0941**
Number of Participants Analyzed [units: participants]	**34**	**34**
Change From Baseline in Hemoglobin A1c (HbA1c) Level [units: % HbA1c] Least Squares Mean (95% Confidence Interval)	**-0.15 (-0.65 to 0.34)**	**-0.26 (-0.76 to 0.23)**

Statistical Analysis 1 for Change From Baseline in Hemoglobin A1c (HbA1c) Level

Groups [1]	All groups
Method [2]	Longitudinal Data Analysis (LDA) model

P Value [3]	0.745
Mean Difference (Net) [4]	-0.11
95% Confidence Interval	-0.81 to 0.58

[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. Primary: Number of Participants Who Experienced One or More Episodes of Hypoglycemia (Symptomatic or Asymptomatic) [Time Frame: From first dose of study drug (Week 0) to last dose of study drug (Week 20)]

Measure Type	Primary
Measure Title	Number of Participants Who Experienced One or More Episodes of Hypoglycemia (Symptomatic or Asymptomatic)
Measure Description	Hypoglycemic episodes - with or without symptoms - are defined as a fingerstick glucose measurement of ≤70 mg/dL (3.9 mmol/L). Excludes data after initiation of glycemic rescue therapy.
Time Frame	From first dose of study drug (Week 0) to last dose of study drug (Week 20)
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 Participants as Treated Population, which consisted of all randomized participants who took at least one dose of study drug (MK-0941 or Placebo).

Reporting Groups

	Description
Placebo	Participants receiving Placebo tablets 3 times daily plus insulin injection once daily
MK-0941	Participants receiving MK-0941 tablets 3 times daily plus insulin injection once daily

Measured Values

	Placebo	**MK-0941**
Number of Participants Analyzed [units: participants]	**34**	**34**
Number of Participants Who Experienced One or More Episodes of Hypoglycemia (Symptomatic or Asymptomatic)	**6**	**8**

[units: participants]		

Statistical Analysis 1 for Number of Participants Who Experienced One or More Episodes of Hypoglycemia (Symptomatic or Asymptomatic)

Groups [1]	All groups
Method [2]	Miettinen & Nurminen method
P Value [3]	0.537
Proportions [4]	5.9
95% Confidence Interval	-13.7 to 25.4

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	Between-treatment difference (MK-0941 group minus Placebo group) in the percentage of participants who experienced one or more episodes of hypoglycemia.
[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	From Screening Visit 2 (Week -10) through to 2 weeks after last dose of randomized study drug (up to 32 weeks)
Additional Description	Reporting of serious AEs includes data after initiation of glycemic rescue therapy. Reporting of non-serious AEs excludes data after initiation of glycemic rescue therapy.

Reporting Groups

	Description
Placebo	Participants receiving Placebo tablets 3 times daily plus insulin injection once daily
MK-0941	Participants receiving MK-0941 tablets 3 times daily plus insulin injection once daily

Serious Adverse Events

	Placebo	MK-0941
Total, serious adverse events		
# participants affected / at risk	**1/34 (2.94%)**	**1/34 (2.94%)**
Gastrointestinal disorders		
Abdominal pain upper † 1		

# participants affected / at risk	0/34 (0.00%)	1/34 (2.94%)
# events	0	1
Metabolism and nutrition disorders		
Hypoglycemia † 1		
# participants affected / at risk	1/34 (2.94%)	0/34 (0.00%)
# events	1	0

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA 13.0

Other Adverse Events

Hide Other Adverse Events

Time Frame	From Screening Visit 2 (Week -10) through to 2 weeks after last dose of randomized study drug (up to 32 weeks)
Additional Description	Reporting of serious AEs includes data after initiation of glycemic rescue therapy. Reporting of non-serious AEs excludes data after initiation of glycemic rescue therapy.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Placebo	Participants receiving Placebo tablets 3 times daily plus insulin injection once daily
MK-0941	Participants receiving MK-0941 tablets 3 times daily plus insulin injection once daily

Other Adverse Events

	Placebo	MK-0941
Total, other (not including serious) adverse events		
# participants affected / at risk	13/34 (38.24%)	11/34 (32.35%)
General disorders		
Fatigue † 1		
# participants affected / at risk	2/34 (5.88%)	0/34 (0.00%)
# events	3	0
Infections and infestations		
Nasopharyngitis † 1		
# participants affected / at risk	2/34 (5.88%)	0/34 (0.00%)
# events	2	0
Metabolism and nutrition disorders		
Hypoglycaemia † 1		
# participants affected / at risk	4/34 (11.76%)	8/34 (23.53%)

# events	9	50
Musculoskeletal and connective tissue disorders		
Back pain † 1		
# participants affected / at risk	2/34 (5.88%)	2/34 (5.88%)
# events	2	2
Myalgia † 1		
# participants affected / at risk	3/34 (8.82%)	0/34 (0.00%)
# events	4	0
Pain in extremity † 1		
# participants affected / at risk	0/34 (0.00%)	2/34 (5.88%)
# events	0	2
Nervous system disorders		
Headache † 1		
# participants affected / at risk	2/34 (5.88%)	2/34 (5.88%)
# events	2	2
Psychiatric disorders		
Insomnia † 1		
# participants affected / at risk	0/34 (0.00%)	2/34 (5.88%)
# events	0	2

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA 13.0

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: After multicenter publication or 24 months after study completion, whichever comes first, an investigator may publish the results for their study site only. Sponsor can review publications 60 days prior to submission.

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

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00824616 History of Changes
Other Study ID Numbers:	0941-018 2009_516 (Other Identifier: Merck Registration ID) MK-0941-018 (Other Identifier: Merck Protocol ID)
Study First Received:	January 16, 2009
Results First Received:	July 17, 2012
Last Updated:	July 21, 2015
Health Authority:	United States: Food and Drug Administration

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