Dose Range Finding Study of MK-0941 in Patients With Type 2 Diabetes Mellitus on Insulin (MK-0941-007 AM3 EXT1 AM1)(TERMINATED)

This study has been terminated.

Sponsor:
Merck Sharp & Dohme Corp.

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

ClinicalTrials.gov Identifier:
NCT00767000

First received: October 3, 2008
Last updated: February 2, 2015
Last verified: February 2015
History of Changes

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Purpose

The purpose of this study is to test the effect of MK-0941 as add-on therapy for participants taking insulin for type 2 diabetes mellitus. The primary hypotheses of this study are that treatment with MK-0941 added to insulin will provide greater reduction in hemoglobin A1c (HbA1c) level than will placebo added to insulin at 14 weeks, and that MK-0941 will be well-tolerated at 1 or more doses that demonstrate efficacy.

Condition	Intervention	Phase
Diabetes Mellitus, Type 2	Drug: MK-0941 Drug: Comparator: Placebo Biological: Lantus Drug: Metformin	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 IIb, Multicenter, Randomized, Double-Blind, Placebo-Controlled Dose-Range Finding Clinical Trial of MK0941 in Patients With Type 2 Diabetes Mellitus With Inadequate Glycemic Control on Insulin

Resource links provided by NLM:

Genetics Home Reference related topics: hereditary multiple exostoses

MedlinePlus related topics: Diabetes Type 2

Drug Information available for: Metformin Insulin Insulin glargine

U.S. FDA Resources

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

Primary Outcome Measures:

- Change in Hemoglobin A1c (HbA1c) Level [Time Frame: Baseline and Weeks 14, 54, 106, and 158] [Designated as safety issue: No]

  Least square means change from baseline in HbA1c. HbA1c represents the percentage of glycated hemoglobin. A negative number means reduction in HbA1c level.

- Percentage of Participants Who Experienced at Least One Adverse Event [Time Frame: Entire study including 54-week study and 104-week extension] [Designated as safety issue: Yes]
- Percentage of Participants Who Discontinued Study Medication Due to an Adverse Event [Time Frame: Entire study including 54-week study and 104-week extension] [Designated as safety issue: Yes]

Secondary Outcome Measures:

- Change in the Two-hour Post Meal Glucose Level [Time Frame: Baseline and Weeks 14, 54, 106, and 158] [Designated as safety issue: No]

  Least squares mean change from baseline in 2-hour post meal glucose level.

- Change in the Fasting Plasma Glucose Level [Time Frame: Baseline and Weeks 14, 54, 106, and 158] [Designated as safety issue: No]

  Least squares mean change from baseline in fasting plasma glucose.

- Percentage of Participants Who Achieve an HbA1c of <7.0% [Time Frame: Weeks 106 and 158] [Designated as safety issue: No]
- Percentage of Participants Achieving an HbA1c of <7.0% at Week 54 Who Maintain an HbA1c of <7.0% [Time Frame: Weeks 54, 106 and 158] [Designated as safety issue: No]

Enrollment:	813
Study Start Date:	October 2008
Study Completion Date:	June 2010
Primary Completion Date:	April 2010 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: MK-0941 10 mg	Drug: MK-0941 MK-0941 tablets three times daily Biological: Lantus Lantus injection once daily Other Name: Insulin glargine injection Drug: Metformin Metformin ≥1500 mg/day at a stable dose for at least 6 weeks before Screening and for the duration of the study. The number of randomized participants who receive metformin will be capped at 70% of enrollment.
Experimental: MK-0941 20 mg	Drug: MK-0941 MK-0941 tablets three times daily Biological: Lantus Lantus injection once daily Other Name: Insulin glargine injection Drug: Metformin Metformin ≥1500 mg/day at a stable dose for at least 6 weeks before Screening and for the duration of the study. The number of randomized participants who receive metformin will be capped at 70% of enrollment.
Experimental: MK-0941 30 mg	Drug: MK-0941 MK-0941 tablets three times daily Biological: Lantus Lantus injection once daily Other Name: Insulin glargine injection Drug: Metformin Metformin ≥1500 mg/day at a stable dose for at least 6 weeks before Screening and for the duration of the study. The

	number of randomized participants who receive metformin will be capped at 70% of enrollment.
Experimental: MK-0941 40 mg	Drug: MK-0941 MK-0941 tablets three times daily Biological: Lantus Lantus injection once daily Other Name: Insulin glargine injection Drug: Metformin Metformin ≥1500 mg/day at a stable dose for at least 6 weeks before Screening and for the duration of the study. The number of randomized participants who receive metformin will be capped at 70% of enrollment.
Placebo Comparator: Placebo	Drug: Comparator: Placebo Matching placebo to MK-0941 three times daily Biological: Lantus Lantus injection once daily Other Name: Insulin glargine injection Drug: Metformin Metformin ≥1500 mg/day at a stable dose for at least 6 weeks before Screening and for the duration of the study. The number of randomized participants who receive metformin will be capped at 70% of enrollment.

Detailed Description:

This study is a 54-week randomized, double-blind base study with an optional 104-week extension study (MK-0941-007-11). Beginning on Week 16, participants not randomized to the maximum dose of MK-0941 could up-titrate to MK-0941 40 mg three times daily. Participants who complete the 54-week base study are eligible to enter the extension study and will remain in the treatment group to which they were assigned in the base study.

Eligibility

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

Criteria

Inclusion Criteria:

- has type 2 diabetes mellitus
- has body mass index >20 and <43 kg/m^2
- is a male, or a female who is unlikely to conceive
- currently on a stable dose of insulin with or without metformin for Type 2 diabetes mellitus

Extension Study Inclusion Criteria:

- completed the base study either on double-blind study medication or as part of the post-treatment follow up population
- had ≥85% compliance with double-blind and open-label medication during the base study double-blind treatment period

Exclusion Criteria:

- has any history of Type 1 diabetes mellitus or ketoacidosis
- has received more that 1 week of thiazolidinedione (such as pioglitazone or rosiglitazone) therapy or injectable increatin-based therapy (such as Byetta) within the prior 8 weeks
- has had ≥2 episodes during their lifetime or >1 episode within the past year resulting in hypoglycemic seizures, comas, or unconsciousness
- is on a weight loss program and is not in the maintenance phase, or patient is taking a weight loss medication (e.g., orlistat, sibutramine, rimonabant) within 8 weeks of Visit 1
- has undergone surgery within 30 days prior to Visit 1 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: NCT00767000

Sponsors and Collaborators

Merck Sharp & Dohme Corp.

Investigators

Study Director: Medical Monitor Merck Sharp & Dohme Corp.

More Information

Publications:

Meininger GE, Scott R, Alba M, Shentu Y, Luo E, Amin H, Davies MJ, Kaufman KD, Goldstein BJ. Effects of MK-0941, a novel glucokinase activator, on glycemic control in insulin-treated patients with type 2 diabetes. Diabetes Care. 2011 Dec;34(12):2560-6. doi: 10.2337/dc11-1200. Epub 2011 Oct 12.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00767000 History of Changes
Other Study ID Numbers:	0941-007 2008_557
Study First Received:	October 3, 2008
Results First Received:	June 19, 2012
Last Updated:	February 2, 2015
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 April 14, 2016

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Dose Range Finding Study of MK-0941 in Patients With Type 2 Diabetes Mellitus on Insulin (MK-0941-007 AM3 EXT1 AM1)(TERMINATED)

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Sponsor:
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Information provided by (Responsible Party):
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ClinicalTrials.gov Identifier:
NCT00767000

First received: October 3, 2008
Last updated: February 2, 2015
Last verified: February 2015
History of Changes

Results First Received: June 19, 2012

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:	Diabetes Mellitus, Type 2
Interventions:	Drug: MK-0941 Drug: Comparator: Placebo Biological: Lantus Drug: Metformin

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
MK-0941 10 mg	MK-0941 10 mg three times daily plus insulin once daily with or without metformin
MK-0941 20 mg	MK-0941 20 mg three times daily plus insulin once daily with or without metformin
MK-0941 30 mg	MK-0941 30 mg three times daily plus insulin once daily with or without metformin
MK-0941 40 mg	MK-0941 40 mg three times daily plus insulin once daily with or without metformin
Placebo	Placebo three times daily plus insulin once daily with or without metformin

Participant Flow for 2 periods

Period 1: 54-week Study

	MK-0941 10 mg	MK-0941 20 mg	MK-0941 30 mg	MK-0941 40 mg	Placebo
STARTED	119	117	117	229 [1]	231 [1]
COMPLETED	11	4	8	4	7
NOT COMPLETED	108	113	109	225	224
Adverse Event	4	6	6	8	4
Creaninine/creatinine clearance	2	1	2	2	4
Hyperglycemia	0	0	1	0	1
Hypoglycemia	0	1	0	0	0
Interruption of study medication	0	0	1	0	0
Lack of Efficacy	2	0	1	0	5
Lost to Follow-up	4	0	1	4	2
Physician Decision	4	0	1	1	1
Progressive disease	0	0	1	0	0
Protocol Violation	0	0	1	2	0
Withdrawal by Subject	2	3	5	11	13
Study terminated by sponsor	90	102	89	196	194
Reason not reported	0	0	0	1	0

[1] Includes additional participants enrolled to enhance evaluation of the safety profile of MK-0941

Period 2: Optional 104-week Extension

	MK-0941 10 mg	MK-0941 20 mg	MK-0941 30 mg	MK-0941 40 mg	Placebo
STARTED	7 [1]	3 [1]	7 [1]	2 [1]	4 [1]
COMPLETED	0	0	0	0	0
NOT COMPLETED	7	3	7	2	4

Study terminated by sponsor	**7**	**3**	**7**	**2**	**4**

[1] The extension study was optional. Not all participants completing the 54-week study continued.

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
MK-0941 10 mg	MK-0941 10 mg three times daily plus insulin once daily with or without metformin
MK-0941 20 mg	MK-0941 20 mg three times daily plus insulin once daily with or without metformin
MK-0941 30 mg	MK-0941 30 mg three times daily plus insulin once daily with or without metformin
MK-0941 40 mg	MK-0941 40 mg three times daily plus insulin once daily with or without metformin
Placebo	Placebo three times daily plus insulin once daily with or without metformin
Total	Total of all reporting groups

Baseline Measures

	MK-0941 10 mg	**MK-0941 20 mg**	**MK-0941 30 mg**	**MK-0941 40 mg**	**Placebo**	**Total**
Number of Participants [units: participants]	**119**	**117**	**117**	**229**	**231**	**813**
Age, Customized [units: participants]						
26 to 71 years	**119**	**117**	**117**	**229**	**231**	**813**
Gender [units: participants]						
Female	**67**	**57**	**54**	**123**	**115**	**416**
Male	**52**	**60**	**63**	**106**	**116**	**397**

Outcome Measures

Hide All Outcome Measures

1. Primary: Change in Hemoglobin A1c (HbA1c) Level [Time Frame: Baseline and Weeks 14, 54, 106, and 158]

Measure Type	Primary

Measure Title	Change in Hemoglobin A1c (HbA1c) Level
Measure Description	Least square means change from baseline in HbA1c. HbA1c represents the percentage of glycated hemoglobin. A negative number means reduction in HbA1c level.
Time Frame	Baseline and Weeks 14, 54, 106, and 158
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. The additional participants added to the MK-0941 40 mg and placebo arms to enhance evaluation of safety were not included in the analysis.

Reporting Groups

	Description
MK-0941 10 mg	MK-0941 10 mg three times daily plus insulin once daily with or without metformin
MK-0941 20 mg	MK-0941 20 mg three times daily plus insulin once daily with or without metformin
MK-0941 30 mg	MK-0941 30 mg three times daily plus insulin once daily with or without metformin
MK-0941 40 mg	MK-0941 40 mg three times daily plus insulin once daily with or without metformin
Placebo	Placebo three times daily plus insulin once daily with or without metformin

Measured Values

	MK-0941 10 mg	**MK-0941 20 mg**	**MK-0941 30 mg**	**MK-0941 40 mg**	**Placebo**
Number of Participants Analyzed [units: participants]	**118**	**117**	**117**	**118**	**115**
Change in Hemoglobin A1c (HbA1c) Level [units: Percent HbA1c] Least Squares Mean (95% Confidence Interval)					
Week 14	**-0.59 (-0.80 to -0.38)**	**-0.72 (-0.92 to -0.52)**	**-0.89 (-1.10 to -0.69)**	**-0.83 (-1.03 to -0.62)**	**-0.08 (-0.28 to 0.13)**
Week 54 (no participants analyzed)	**NA** [1]	**NA** [1]	**NA** [1]	**NA** [1]	**NA** [1]
Week 106 (no participants analyzed)	**NA** [1]	**NA** [1]	**NA** [1]	**NA** [1]	**NA** [1]
Week 158 (no participants analyzed)	**NA** [1]	**NA** [1]	**NA** [1]	**NA** [1]	**NA** [1]

[1] Due to early termination and small numbers of participants, no efficacy analyses were performed at Weeks 54, 106, or 158

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

[1]	

Groups	MK-0941 10 mg vs. Placebo
Method [2]	Constrained longitudinal model
P Value [3]	<0.001
Least Squares Mean Difference [4]	-0.51
95% Confidence Interval	-0.80 to -0.22

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	Analysis for change from baseline to Week 14
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 2 for Change in Hemoglobin A1c (HbA1c) Level

Groups [1]	MK-0941 20 mg vs. Placebo
Method [2]	Constrained longitudinal model
P Value [3]	<0.001
Least Squares Mean Difference [4]	-0.64
95% Confidence Interval	-0.93 to -0.36

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	Analysis for change from baseline to Week 14
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 3 for Change in Hemoglobin A1c (HbA1c) Level

Groups [1]	MK-0941 30 mg vs. Placebo
Method [2]	Contrained longitudinal model
P Value [3]	<0.001
Least Squares Mean Difference [4]	-0.81
95% Confidence Interval	

	-1.10 to -0.53

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	Analysis for change from baseline to Week 14
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 4 for Change in Hemoglobin A1c (HbA1c) Level

Groups [1]	MK-0941 40 mg vs. Placebo
Method [2]	Constrained longitudinal model
P Value [3]	<0.001
Least Squares Mean Difference [4]	-0.75
95% Confidence Interval	-1.04 to -0.46

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	Analysis for change from baseline to Week 14
[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: Percentage of Participants Who Experienced at Least One Adverse Event [Time Frame: Entire study including 54-week study and 104-week extension]

Measure Type	Primary
Measure Title	Percentage of Participants Who Experienced at Least One Adverse Event
Measure Description	No text entered.
Time Frame	Entire study including 54-week study and 104-week extension
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.

Full analysis set. Includes additional participants enrolled in the MK-0941 40 mg and placebo groups to enhance evaluation of the safety profile of MK-0941.

Reporting Groups

	Description
MK-0941 10 mg	MK-0941 10 mg three times daily plus insulin once daily with or without metformin
MK-0941 20 mg	MK-0941 20 mg three times daily plus insulin once daily with or without metformin
MK-0941 30 mg	MK-0941 30 mg three times daily plus insulin once daily with or without metformin
MK-0941 40 mg	MK-0941 40 mg three times daily plus insulin once daily with or without metformin
Placebo	Placebo three times daily plus insulin once daily with or without metformin

Measured Values

	MK-0941 10 mg	MK-0941 20 mg	MK-0941 30 mg	MK-0941 40 mg	Placebo
Number of Participants Analyzed [units: participants]	**119**	**117**	**117**	**229**	**231**
Percentage of Participants Who Experienced at Least One Adverse Event [units: percentage of participants]	**80.7**	**79.5**	**80.3**	**65.5**	**65.4**

No statistical analysis provided for Percentage of Participants Who Experienced at Least One Adverse Event

3. Primary: Percentage of Participants Who Discontinued Study Medication Due to an Adverse Event [Time Frame: Entire study including 54-week study and 104-week extension]

Measure Type	Primary
Measure Title	Percentage of Participants Who Discontinued Study Medication Due to an Adverse Event
Measure Description	No text entered.
Time Frame	Entire study including 54-week study and 104-week extension
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
MK-0941 10 mg	MK-0941 10 mg three times daily plus insulin once daily with or without metformin

MK-0941 20 mg	MK-0941 20 mg three times daily plus insulin once daily with or without metformin
MK-0941 30 mg	MK-0941 30 mg three times daily plus insulin once daily with or without metformin
MK-0941 40 mg	MK-0941 40 mg three times daily plus insulin once daily with or without metformin
Placebo	Placebo three times daily plus insulin once daily with or without metformin

Measured Values

	MK-0941 10 mg	MK-0941 20 mg	MK-0941 30 mg	MK-0941 40 mg	Placebo
Number of Participants Analyzed [units: participants]	**119**	**117**	**117**	**229**	**231**
Percentage of Participants Who Discontinued Study Medication Due to an Adverse Event [units: percentage of participants]	**3.4**	**5.1**	**6.8**	**3.1**	**1.7**

No statistical analysis provided for Percentage of Participants Who Discontinued Study Medication Due to an Adverse Event

4. Secondary: Change in the Two-hour Post Meal Glucose Level [Time Frame: Baseline and Weeks 14, 54, 106, and 158]

Measure Type	Secondary
Measure Title	Change in the Two-hour Post Meal Glucose Level
Measure Description	Least squares mean change from baseline in 2-hour post meal glucose level.
Time Frame	Baseline and Weeks 14, 54, 106, and 158
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. The additional participants added to the MK-0941 40 mg and placebo arms to enhance evaluation of safety were not included in the analysis.

Reporting Groups

	Description
MK-0941 10 mg	MK-0941 10 mg three times daily plus insulin once daily with or without metformin
MK-0941 20 mg	MK-0941 20 mg three times daily plus insulin once daily with or without metformin
MK-0941 30 mg	MK-0941 30 mg three times daily plus insulin once daily with or without metformin
MK-0941 40 mg	MK-0941 40 mg three times daily plus insulin once daily with or without metformin
Placebo	Placebo three times daily plus insulin once daily with or without metformin

Measured Values

	MK-0941 10 mg	MK-0941 20 mg	MK-0941 30 mg	MK-0941 40 mg	Placebo
Number of Participants Analyzed [units: participants]	112	114	113	115	111
Change in the Two-hour Post Meal Glucose Level [units: mg/dL] Least Squares Mean (95% Confidence Interval)					
Week 14	-39.0 (-52.0 to -25.1)	-29.2 (-42.5 to -15.9)	-37.4 (-51.2 to -23.6)	-39.3 (-53.1 to -25.5)	-2.4 (-16.0 to 11.2)
Week 54 (no participants analyzed)	NA [1]	NA [1]	NA [1]	NA [1]	NA [1]
Week 106 (no participants analyzed)	NA [1]	NA [1]	NA [1]	NA [1]	NA [1]
Week 158 (no participants analyzed)	NA [1]	NA [1]	NA [1]	NA [1]	NA [1]

[1] Due to early termination and small numbers of participants, no efficacy analyses were performed at Weeks 54, 106, or 158

Statistical Analysis 1 for Change in the Two-hour Post Meal Glucose Level

Groups [1]	MK-0941 10 mg vs. Placebo
Method [2]	Constrained longitudial model
P Value [3]	<0.001
Least Squares Mean Difference [4]	-36.6
95% Confidence Interval	-55.6 to -17.5

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	Analysis for change from baseline to Week 14
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 2 for Change in the Two-hour Post Meal Glucose Level

Groups [1]	MK-0941 20 mg vs. Placebo
Method [2]	Constrained longitudinal model

P Value [3]	0.005
Least Squares Mean Difference [4]	-26.7
95% Confidence Interval	-45.4 to -8.1

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	Analysis for change from baseline to Week 14
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 3 for Change in the Two-hour Post Meal Glucose Level

Groups [1]	MK-0941 30 mg vs. Placebo
Method [2]	Constrained longitudinal model
P Value [3]	<0.001
Least Squares Mean Difference [4]	-35.0
95% Confidence Interval	-54.0 to -16.0

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	Analysis for change from baseline to Week 14
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 4 for Change in the Two-hour Post Meal Glucose Level

Groups [1]	MK-0941 40 mg vs. Placebo
Method [2]	Constrained longitudinal model
P Value [3]	<0.001
Least Squares Mean Difference [4]	-36.9
95% Confidence Interval	-55.9 to -17.9

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	Analysis for change from baseline to Week 14

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

5. Secondary: Change in the Fasting Plasma Glucose Level [Time Frame: Baseline and Weeks 14, 54, 106, and 158]

Measure Type	Secondary
Measure Title	Change in the Fasting Plasma Glucose Level
Measure Description	Least squares mean change from baseline in fasting plasma glucose.
Time Frame	Baseline and Weeks 14, 54, 106, and 158
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. The additional participants added to the MK-0941 40 mg and placebo arms to enhance evaluation of safety were not included in the analysis.

Reporting Groups

	Description
MK-0941 10 mg	MK-0941 10 mg three times daily plus insulin once daily with or without metformin
MK-0941 20 mg	MK-0941 20 mg three times daily plus insulin once daily with or without metformin
MK-0941 30 mg	MK-0941 30 mg three times daily plus insulin once daily with or without metformin
MK-0941 40 mg	MK-0941 40 mg three times daily plus insulin once daily with or without metformin
Placebo	Placebo three times daily plus insulin once daily with or without metformin

Measured Values

	MK-0941 10 mg	**MK-0941 20 mg**	**MK-0941 30 mg**	**MK-0941 40 mg**	**Placebo**
Number of Participants Analyzed [units: participants]	**118**	**117**	**117**	**118**	**115**
Change in the Fasting Plasma Glucose Level [units: mg/dL] Least Squares Mean (95% Confidence					

Interval)					
Week 14	-10.0 (-19.9 to 0.0)	-1.5 (-10.9 to 7.9)	-21.1 (-30.9 to -11.2)	-5.0 (-14.9 to 4.8)	-11.8 (-21.4 to -2.1)
Week 54 (no participants analyzed)	NA [1]	NA [1]	NA [1]	NA [1]	NA [1]
Week 106 (no participants analyzed)	NA [1]	NA [1]	NA [1]	NA [1]	NA [1]
Week 158 (no participants analyzed)	NA [1]	NA [1]	NA [1]	NA [1]	NA [1]

[1] Due to early termination and small numbers of participants, no efficacy analyses were performed at Weeks 54, 106, or 158

Statistical Analysis 1 for Change in the Fasting Plasma Glucose Level

Groups [1]	MK-0941 10 mg vs. Placebo
Method [2]	Constrained longitudinal model
P Value [3]	0.791
Least Squares Mean Difference [4]	1.8
95% Confidence Interval	-11.6 to 15.2

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	Analysis for change from baseline to Week 14
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 2 for Change in the Fasting Plasma Glucose Level

Groups [1]	MK-0941 20 mg vs. Placebo
Method [2]	Constrained longitudinal model
P Value [3]	0.121
Least Squares Mean Difference [4]	10.3
95% Confidence Interval	-2.7 to 23.2

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	Analysis for change from baseline to Week 14
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.

[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 3 for Change in the Fasting Plasma Glucose Level

Groups [1]	MK-0941 30 mg vs. Placebo
Method [2]	Constrained longitudinal model
P Value [3]	0.169
Least Squares Mean Difference [4]	-9.3
95% Confidence Interval	-22.6 to 4.0

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	Analysis for change from baseline to Week 14
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 4 for Change in the Fasting Plasma Glucose Level

Groups [1]	MK-0941 40 mg vs. Placebo
Method [2]	Constrained longitudinal model
P Value [3]	0.321
Least Squares Mean Difference [4]	6.7
95% Confidence Interval	-6.6 to 20.0

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	Analysis for change from baseline to Week 14
[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.

6. Secondary: Percentage of Participants Who Achieve an HbA1c of <7.0% [Time Frame: Weeks 106 and 158]

Measure Type	Secondary
Measure Title	Percentage of Participants Who Achieve an HbA1c of <7.0%
Measure Description	No text entered.
Time Frame	Weeks 106 and 158
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.
Due to early termination and small numbers of participants, no efficacy analyses were performed at Weeks 106 or 158

Reporting Groups

	Description
MK-0941 10 mg	MK-0941 10 mg three times daily plus insulin once daily with or without metformin
MK-0941 20 mg	MK-0941 20 mg three times daily plus insulin once daily with or without metformin
MK-0941 30 mg	MK-0941 30 mg three times daily plus insulin once daily with or without metformin
MK-0941 40 mg	MK-0941 40 mg three times daily plus insulin once daily with or without metformin
Placebo	Placebo three times daily plus insulin once daily with or without metformin

Measured Values

	MK-0941 10 mg	**MK-0941 20 mg**	**MK-0941 30 mg**	**MK-0941 40 mg**	**Placebo**
Number of Participants Analyzed [units: participants]	**0**	**0**	**0**	**0**	**0**
Percentage of Participants Who Achieve an HbA1c of <7.0%					

No statistical analysis provided for Percentage of Participants Who Achieve an HbA1c of <7.0%

7. Secondary: Percentage of Participants Achieving an HbA1c of <7.0% at Week 54 Who Maintain an HbA1c of <7.0% [Time Frame: Weeks 54, 106 and 158]

Measure Type	Secondary
Measure Title	Percentage of Participants Achieving an HbA1c of <7.0% at Week 54 Who Maintain an HbA1c of <7.0%
Measure Description	No text entered.
Time Frame	Weeks 54, 106 and 158

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.
Due to early termination and small numbers of participants, no efficacy analyses were performed at Weeks 106 or 158

Reporting Groups

	Description
MK-0941 10 mg	MK-0941 10 mg three times daily plus insulin once daily with or without metformin
MK-0941 20 mg	MK-0941 20 mg three times daily plus insulin once daily with or without metformin
MK-0941 30 mg	MK-0941 30 mg three times daily plus insulin once daily with or without metformin
MK-0941 40 mg	MK-0941 40 mg three times daily plus insulin once daily with or without metformin
Placebo	Placebo three times daily plus insulin once daily with or without metformin

Measured Values

	MK-0941 10 mg	**MK-0941 20 mg**	**MK-0941 30 mg**	**MK-0941 40 mg**	**Placebo**
Number of Participants Analyzed [units: participants]	**0**	**0**	**0**	**0**	**0**
Percentage of Participants Achieving an HbA1c of <7.0% at Week 54 Who Maintain an HbA1c of <7.0%					

No statistical analysis provided for Percentage of Participants Achieving an HbA1c of <7.0% at Week 54 Who Maintain an HbA1c of <7.0%

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	Adverse events were collected for the entire study including the 54-week study and 104-week extension
Additional Description	No text entered.

Reporting Groups

	Description
MK-0941 10 mg	MK-0941 10 mg three times daily plus insulin once daily with or without metformin
MK-0941 20 mg	MK-0941 20 mg three times daily plus insulin once daily with or without metformin
MK-0941 30 mg	MK-0941 30 mg three times daily plus insulin once daily with or without metformin

MK-0941 40 mg	MK-0941 40 mg three times daily plus insulin once daily with or without metformin
Placebo	Placebo three times daily plus insulin once daily with or without metformin

Serious Adverse Events

	MK-0941 10 mg	MK-0941 20 mg	MK-0941 30 mg	MK-0941 40 mg	Placebo
Total, serious adverse events					
# participants affected / at risk	**11/119 (9.24%)**	**12/117 (10.26%)**	**11/117 (9.40%)**	**13/229 (5.68%)**	**8/231 (3.46%)**
Cardiac disorders					
Acute coronary syndrome † 1					
# participants affected / at risk	**1/119 (0.84%)**	**0/117 (0.00%)**	**0/117 (0.00%)**	**0/229 (0.00%)**	**0/231 (0.00%)**
# events	**1**	**0**	**0**	**0**	**0**
Acute myocardial infarction † 1					
# participants affected / at risk	**0/119 (0.00%)**	**0/117 (0.00%)**	**0/117 (0.00%)**	**0/229 (0.00%)**	**1/231 (0.43%)**
# events	**0**	**0**	**0**	**0**	**1**
Angina pectoris † 1					
# participants affected / at risk	**2/119 (1.68%)**	**0/117 (0.00%)**	**0/117 (0.00%)**	**0/229 (0.00%)**	**0/231 (0.00%)**
# events	**2**	**0**	**0**	**0**	**0**
Atrial fibrillation † 1					
# participants affected / at risk	**1/119 (0.84%)**	**0/117 (0.00%)**	**0/117 (0.00%)**	**1/229 (0.44%)**	**0/231 (0.00%)**
# events	**1**	**0**	**0**	**1**	**0**
Atrial flutter † 1					
# participants affected / at risk	**1/119 (0.84%)**	**0/117 (0.00%)**	**0/117 (0.00%)**	**0/229 (0.00%)**	**0/231 (0.00%)**
# events	**1**	**0**	**0**	**0**	**0**
Coronary artery disease † 1					
# participants affected / at risk	**0/119 (0.00%)**	**1/117 (0.85%)**	**0/117 (0.00%)**	**0/229 (0.00%)**	**0/231 (0.00%)**
# events	**0**	**1**	**0**	**0**	**0**
Myocardial infarction † 1					
# participants affected / at risk	**0/119 (0.00%)**	**2/117 (1.71%)**	**0/117 (0.00%)**	**0/229 (0.00%)**	**1/231 (0.43%)**
# events	**0**	**2**	**0**	**0**	**1**
Palpitations † 1					
# participants affected / at risk	**1/119 (0.84%)**	**0/117 (0.00%)**	**0/117 (0.00%)**	**0/229 (0.00%)**	**0/231 (0.00%)**

# events	1	0	0	0	0
Eye disorders					
Cataract † 1					
# participants affected / at risk	1/119 (0.84%)	0/117 (0.00%)	0/117 (0.00%)	0/229 (0.00%)	0/231 (0.00%)
# events	1	0	0	0	0
Macular hole † 1					
# participants affected / at risk	0/119 (0.00%)	1/117 (0.85%)	0/117 (0.00%)	0/229 (0.00%)	0/231 (0.00%)
# events	0	1	0	0	0
Macular oedema † 1					
# participants affected / at risk	0/119 (0.00%)	1/117 (0.85%)	0/117 (0.00%)	0/229 (0.00%)	0/231 (0.00%)
# events	0	1	0	0	0
Retinal haemorrhage † 1					
# participants affected / at risk	0/119 (0.00%)	1/117 (0.85%)	0/117 (0.00%)	0/229 (0.00%)	0/231 (0.00%)
# events	0	1	0	0	0
Gastrointestinal disorders					
Constipation † 1					
# participants affected / at risk	0/119 (0.00%)	0/117 (0.00%)	0/117 (0.00%)	1/229 (0.44%)	0/231 (0.00%)
# events	0	0	0	1	0
Diarrhoea † 1					
# participants affected / at risk	0/119 (0.00%)	0/117 (0.00%)	1/117 (0.85%)	0/229 (0.00%)	0/231 (0.00%)
# events	0	0	1	0	0
Upper gastrointestinal haemorrhage † 1					
# participants affected / at risk	0/119 (0.00%)	0/117 (0.00%)	0/117 (0.00%)	1/229 (0.44%)	0/231 (0.00%)
# events	0	0	0	1	0
Vomiting † 1					
# participants affected / at risk	0/119 (0.00%)	0/117 (0.00%)	1/117 (0.85%)	0/229 (0.00%)	0/231 (0.00%)
# events	0	0	1	0	0
General disorders					
Chest pain † 1					
# participants affected / at risk	0/119 (0.00%)	0/117 (0.00%)	1/117 (0.85%)	0/229 (0.00%)	0/231 (0.00%)
# events	0	0	2	0	0
† 1					

Cyst rupture					
# participants affected / at risk	**0/119 (0.00%)**	**0/117 (0.00%)**	**1/117 (0.85%)**	**0/229 (0.00%)**	**0/231 (0.00%)**
# events	**0**	**0**	**1**	**0**	**0**
Death † 1					
# participants affected / at risk	**0/119 (0.00%)**	**0/117 (0.00%)**	**0/117 (0.00%)**	**1/229 (0.44%)**	**0/231 (0.00%)**
# events	**0**	**0**	**0**	**1**	**0**
Hepatobiliary disorders					
Hepatic cirrhosis † 1					
# participants affected / at risk	**0/119 (0.00%)**	**0/117 (0.00%)**	**0/117 (0.00%)**	**1/229 (0.44%)**	**0/231 (0.00%)**
# events	**0**	**0**	**0**	**1**	**0**
Immune system disorders					
Sarcoidosis † 1					
# participants affected / at risk	**0/119 (0.00%)**	**0/117 (0.00%)**	**0/117 (0.00%)**	**1/229 (0.44%)**	**0/231 (0.00%)**
# events	**0**	**0**	**0**	**1**	**0**
Infections and infestations					
Anal abscess † 1					
# participants affected / at risk	**1/119 (0.84%)**	**0/117 (0.00%)**	**0/117 (0.00%)**	**0/229 (0.00%)**	**0/231 (0.00%)**
# events	**1**	**0**	**0**	**0**	**0**
Cellulitis † 1					
# participants affected / at risk	**0/119 (0.00%)**	**0/117 (0.00%)**	**0/117 (0.00%)**	**1/229 (0.44%)**	**0/231 (0.00%)**
# events	**0**	**0**	**0**	**1**	**0**
Gangrene † 1					
# participants affected / at risk	**0/119 (0.00%)**	**0/117 (0.00%)**	**0/117 (0.00%)**	**0/229 (0.00%)**	**1/231 (0.43%)**
# events	**0**	**0**	**0**	**0**	**1**
Gastroenteritis † 1					
# participants affected / at risk	**0/119 (0.00%)**	**1/117 (0.85%)**	**0/117 (0.00%)**	**0/229 (0.00%)**	**0/231 (0.00%)**
# events	**0**	**1**	**0**	**0**	**0**
Postoperative wound infection † 1					
# participants affected / at risk	**0/119 (0.00%)**	**1/117 (0.85%)**	**0/117 (0.00%)**	**0/229 (0.00%)**	**0/231 (0.00%)**
# events	**0**	**1**	**0**	**0**	**0**
Respiratory tract infection † 1					
# participants affected / at risk	**0/119 (0.00%)**	**0/117 (0.00%)**	**0/117 (0.00%)**	**1/229 (0.44%)**	**0/231 (0.00%)**

# events	0	0	0	1	0
Staphylococcal infection † 1					
# participants affected / at risk	0/119 (0.00%)	1/117 (0.85%)	0/117 (0.00%)	0/229 (0.00%)	0/231 (0.00%)
# events	0	1	0	0	0
Urinary tract infection † 1					
# participants affected / at risk	0/119 (0.00%)	0/117 (0.00%)	0/117 (0.00%)	1/229 (0.44%)	0/231 (0.00%)
# events	0	0	0	1	0
Viral infection † 1					
# participants affected / at risk	1/119 (0.84%)	0/117 (0.00%)	0/117 (0.00%)	0/229 (0.00%)	0/231 (0.00%)
# events	1	0	0	0	0
Wound infection † 1					
# participants affected / at risk	0/119 (0.00%)	0/117 (0.00%)	0/117 (0.00%)	1/229 (0.44%)	0/231 (0.00%)
# events	0	0	0	1	0
Injury, poisoning and procedural complications					
Ankle fracture † 1					
# participants affected / at risk	0/119 (0.00%)	0/117 (0.00%)	0/117 (0.00%)	0/229 (0.00%)	1/231 (0.43%)
# events	0	0	0	0	1
Femur fracture † 1					
# participants affected / at risk	0/119 (0.00%)	0/117 (0.00%)	1/117 (0.85%)	0/229 (0.00%)	0/231 (0.00%)
# events	0	0	1	0	0
Foot fracture † 1					
# participants affected / at risk	0/119 (0.00%)	1/117 (0.85%)	0/117 (0.00%)	0/229 (0.00%)	0/231 (0.00%)
# events	0	1	0	0	0
Head injury † 1					
# participants affected / at risk	0/119 (0.00%)	0/117 (0.00%)	2/117 (1.71%)	0/229 (0.00%)	0/231 (0.00%)
# events	0	0	2	0	0
Pelvic fracture † 1					
# participants affected / at risk	0/119 (0.00%)	0/117 (0.00%)	0/117 (0.00%)	1/229 (0.44%)	0/231 (0.00%)
# events	0	0	0	1	0
Rib fracture † 1					
# participants affected / at risk	0/119 (0.00%)	0/117 (0.00%)	0/117 (0.00%)	1/229 (0.44%)	0/231 (0.00%)

# events	0	0	0	1	0
Metabolism and nutrition disorders					
Hyperglycaemia † 1					
# participants affected / at risk	0/119 (0.00%)	0/117 (0.00%)	1/117 (0.85%)	0/229 (0.00%)	0/231 (0.00%)
# events	0	0	1	0	0
Musculoskeletal and connective tissue disorders					
Musculoskeletal chest pain † 1					
# participants affected / at risk	0/119 (0.00%)	0/117 (0.00%)	0/117 (0.00%)	1/229 (0.44%)	0/231 (0.00%)
# events	0	0	0	1	0
Spinal column stenosis † 1					
# participants affected / at risk	1/119 (0.84%)	0/117 (0.00%)	0/117 (0.00%)	0/229 (0.00%)	0/231 (0.00%)
# events	1	0	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
Colon cancer stage 0 † 1					
# participants affected / at risk	0/119 (0.00%)	0/117 (0.00%)	1/117 (0.85%)	0/229 (0.00%)	0/231 (0.00%)
# events	0	0	1	0	0
Colon cancer stage I † 1					
# participants affected / at risk	1/119 (0.84%)	0/117 (0.00%)	0/117 (0.00%)	0/229 (0.00%)	0/231 (0.00%)
# events	1	0	0	0	0
Hepatic neoplasm malignant † 1					
# participants affected / at risk	0/119 (0.00%)	0/117 (0.00%)	0/117 (0.00%)	1/229 (0.44%)	0/231 (0.00%)
# events	0	0	0	1	0
Thyroid cancer † 1					
# participants affected / at risk	0/119 (0.00%)	0/117 (0.00%)	0/117 (0.00%)	0/229 (0.00%)	1/231 (0.43%)
# events	0	0	0	0	1
Thyroid neoplasm † 1					
# participants affected / at risk	0/119 (0.00%)	0/117 (0.00%)	1/117 (0.85%)	0/229 (0.00%)	0/231 (0.00%)
# events	0	0	1	0	0
Nervous system disorders					
Cerebral infarction † 1					
# participants affected / at risk	0/119 (0.00%)	0/117 (0.00%)	1/117 (0.85%)	0/229 (0.00%)	1/231 (0.43%)

# events	0	0	1	0	1
Cerebrovascular accident † 1					
# participants affected / at risk	0/119 (0.00%)	1/117 (0.85%)	0/117 (0.00%)	0/229 (0.00%)	0/231 (0.00%)
# events	0	1	0	0	0
Diabetic neuropathy † 1					
# participants affected / at risk	0/119 (0.00%)	0/117 (0.00%)	0/117 (0.00%)	1/229 (0.44%)	0/231 (0.00%)
# events	0	0	0	1	0
Headache † 1					
# participants affected / at risk	0/119 (0.00%)	0/117 (0.00%)	1/117 (0.85%)	0/229 (0.00%)	0/231 (0.00%)
# events	0	0	1	0	0
Syncope † 1					
# participants affected / at risk	0/119 (0.00%)	1/117 (0.85%)	0/117 (0.00%)	0/229 (0.00%)	1/231 (0.43%)
# events	0	1	0	0	1
Renal and urinary disorders					
Calculus ureteric † 1					
# participants affected / at risk	0/119 (0.00%)	0/117 (0.00%)	0/117 (0.00%)	1/229 (0.44%)	0/231 (0.00%)
# events	0	0	0	1	0
Calculus urinary † 1					
# participants affected / at risk	0/119 (0.00%)	0/117 (0.00%)	0/117 (0.00%)	0/229 (0.00%)	1/231 (0.43%)
# events	0	0	0	0	1
Reproductive system and breast disorders					
Endometrial hyperplasia † 1					
# participants affected / at risk	0/119 (0.00%)	2/117 (1.71%)	0/117 (0.00%)	0/229 (0.00%)	0/231 (0.00%)
# events	0	2	0	0	0
Ovarian mass † 1					
# participants affected / at risk	1/119 (0.84%)	0/117 (0.00%)	0/117 (0.00%)	0/229 (0.00%)	0/231 (0.00%)
# events	1	0	0	0	0
Respiratory, thoracic and mediastinal disorders					
Dyspnoea † 1					
# participants affected / at risk	0/119 (0.00%)	1/117 (0.85%)	0/117 (0.00%)	0/229 (0.00%)	0/231 (0.00%)
# events	0	1	0	0	0

Vascular disorders					
Arterial haemorrhage † 1					
# participants affected / at risk	**0/119 (0.00%)**	**1/117 (0.85%)**	**0/117 (0.00%)**	**0/229 (0.00%)**	**0/231 (0.00%)**
# events	**0**	**1**	**0**	**0**	**0**
Hypertension † 1					
# participants affected / at risk	**1/119 (0.84%)**	**0/117 (0.00%)**	**0/117 (0.00%)**	**0/229 (0.00%)**	**0/231 (0.00%)**
# events	**1**	**0**	**0**	**0**	**0**
Hypertensive crisis † 1					
# participants affected / at risk	**0/119 (0.00%)**	**0/117 (0.00%)**	**0/117 (0.00%)**	**1/229 (0.44%)**	**0/231 (0.00%)**
# events	**0**	**0**	**0**	**1**	**0**

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

Other Adverse Events

Hide Other Adverse Events

Time Frame	Adverse events were collected for the entire study including the 54-week study and 104-week extension
Additional Description	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
MK-0941 10 mg	MK-0941 10 mg three times daily plus insulin once daily with or without metformin
MK-0941 20 mg	MK-0941 20 mg three times daily plus insulin once daily with or without metformin
MK-0941 30 mg	MK-0941 30 mg three times daily plus insulin once daily with or without metformin
MK-0941 40 mg	MK-0941 40 mg three times daily plus insulin once daily with or without metformin
Placebo	Placebo three times daily plus insulin once daily with or without metformin

Other Adverse Events

	MK-0941 10 mg	**MK-0941 20 mg**	**MK-0941 30 mg**	**MK-0941 40 mg**	**Placebo**
Total, other (not including serious) adverse events					

# participants affected / at risk	74/119 (62.18%)	75/117 (64.10%)	78/117 (66.67%)	120/229 (52.40%)	101/231 (43.72%)
Eye disorders					
Cataract † 1					
# participants affected / at risk	10/119 (8.40%)	12/117 (10.26%)	17/117 (14.53%)	10/229 (4.37%)	20/231 (8.66%)
# events	13	16	22	11	20
Diabetic retinopathy † 1					
# participants affected / at risk	3/119 (2.52%)	6/117 (5.13%)	6/117 (5.13%)	4/229 (1.75%)	3/231 (1.30%)
# events	3	8	8	4	3
Gastrointestinal disorders					
Diarrhoea † 1					
# participants affected / at risk	7/119 (5.88%)	7/117 (5.98%)	4/117 (3.42%)	8/229 (3.49%)	11/231 (4.76%)
# events	9	9	4	13	22
Infections and infestations					
Influenza † 1					
# participants affected / at risk	6/119 (5.04%)	4/117 (3.42%)	8/117 (6.84%)	10/229 (4.37%)	8/231 (3.46%)
# events	7	4	9	14	10
Nasopharyngitis † 1					
# participants affected / at risk	8/119 (6.72%)	13/117 (11.11%)	12/117 (10.26%)	12/229 (5.24%)	10/231 (4.33%)
# events	10	14	12	16	12
Upper respiratory tract infection † 1					
# participants affected / at risk	10/119 (8.40%)	6/117 (5.13%)	11/117 (9.40%)	11/229 (4.80%)	6/231 (2.60%)
# events	11	7	16	14	7
Metabolism and nutrition disorders					
Hypoglycaemia † 1					
# participants affected / at risk	57/119 (47.90%)	58/117 (49.57%)	57/117 (48.72%)	94/229 (41.05%)	67/231 (29.00%)
# events	425	475	719	690	350
Musculoskeletal and connective tissue disorders					
Back pain † 1					
# participants affected / at risk	7/119 (5.88%)	1/117 (0.85%)	1/117 (0.85%)	3/229 (1.31%)	6/231 (2.60%)
# events	7	1	1	3	6
Nervous system disorders					
Headache † 1					
# participants affected / at risk	4/119 (3.36%)	12/117 (10.26%)	5/117 (4.27%)	13/229 (5.68%)	7/231 (3.03%)
# events	8	12	6	16	8

† 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: 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
phone: 1-800-672-6372
e-mail: ClinicalTrialsDisclosure@merck.com

Publications of Results:

Meininger GE, Scott R, Alba M, Shentu Y, Luo E, Amin H, Davies MJ, Kaufman KD, Goldstein BJ. Effects of MK-0941, a novel glucokinase activator, on glycemic control in insulin-treated patients with type 2 diabetes. Diabetes Care. 2011 Dec;34(12):2560-6. doi: 10.2337/dc11-1200. Epub 2011 Oct 12.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00767000 History of Changes
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Results First Received:	June 19, 2012
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