Dose-Range Finding Study for MK0893 (0893-008)

This study has been terminated.

(Sufficient data regarding the dose-response to MK-0893 had been obtained from the first cohort of the study to assess the safety and efficacy)

Sponsor:
Merck Sharp & Dohme Corp.

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

ClinicalTrials.gov Identifier:
NCT00479466

First received: May 25, 2007
Last updated: September 8, 2015
Last verified: September 2015
History of Changes

Purpose

A study to compare MK0893 to metformin or placebo for patients with Type 2 diabetes (Diabetes Mellitus).

Condition	Intervention	Phase
Diabetes Mellitus, Type 2	Drug: MK0893 Drug: Metformin Drug: Placebo to MK0893 Drug: Placebo to 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 Multicenter, Double-Blind, Randomized, Placebo and Active Comparator Controlled Dose-Range Finding Study of MK0893 in Patients With Type 2 Diabetes Mellitus Who Have Inadequate Glycemic Control

Resource links provided by NLM:

MedlinePlus related topics: Diabetes Type 2

Drug Information available for: Metformin Metformin hydrochloride

U.S. FDA Resources

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

Primary Outcome Measures:

- Change From Baseline to Week 12 in Fasting Plasma Glucose (FPG) [Time Frame: Week 12] [Designated as safety issue: No]

Secondary Outcome Measures:

- Change From Baseline to Week 12 in Hemoglobin A1c (HbA1c) [Time Frame: Week 12] [Designated as safety issue: No]
- Change From Baseline to Week 12 in 2-Hour Post Prandial Glucose (PPG) [Time Frame: Week 12] [Designated as safety issue: No]

Enrollment:	342
Study Start Date:	July 2007
Study Completion Date:	May 2008
Primary Completion Date:	May 2008 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: MK0893 80 mg MK0893 tablets totaling 80 mg once daily.	Drug: MK0893 MK0893 taken orally once daily; 20 mg and 40 mg tablets used in combination according to dose. Drug: Placebo to MK0893 Dose-matched placebo tablets to MK0893; taken orally once daily. Drug: Placebo to Metformin Dose-matched placebo tablets to metformin (500 mg); taken orally twice daily.
Experimental: MK0893 60 mg MK0893 tablets totaling 60 mg once daily.	Drug: MK0893 MK0893 taken orally once daily; 20 mg and 40 mg tablets used in combination according to dose. Drug: Placebo to MK0893 Dose-matched placebo tablets to MK0893; taken orally once daily. Drug: Placebo to Metformin Dose-matched placebo tablets to metformin (500 mg); taken orally twice daily.
Experimental: MK0893 40 mg MK0893 40 mg tablet once daily.	Drug: MK0893 MK0893 taken orally once daily; 20 mg and 40 mg tablets used in combination according to dose. Drug: Placebo to MK0893 Dose-matched placebo tablets to MK0893; taken orally once daily. Drug: Placebo to Metformin Dose-matched placebo tablets to metformin (500 mg); taken orally twice daily.
Experimental: MK0893 20 mg MK0893 20 mg tablet once daily.	Drug: MK0893 MK0893 taken orally once daily; 20 mg and 40 mg tablets used in combination according to dose. Drug: Placebo to MK0893 Dose-matched placebo tablets to MK0893; taken orally once daily. Drug: Placebo to Metformin Dose-matched placebo tablets to metformin (500 mg); taken orally twice daily.
Active Comparator: Metformin Metformin HCL 500 mg tablet twice daily BID titrating up to 1000 mg twice daily over 3 weeks.	Drug: Metformin Metformin HCL 500 mg tablet twice daily titrating up to 1000 mg twice daily over 3 weeks. Drug: Placebo to MK0893 Dose-matched placebo tablets to MK0893; taken orally once daily.
Placebo Comparator: Placebo PLA tablets. 12 week treatment period.	Drug: Placebo to MK0893 Dose-matched placebo tablets to MK0893; taken orally once daily. Drug: Placebo to Metformin

	Dose-matched placebo tablets to metformin (500 mg); taken orally twice daily.

Eligibility

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

Criteria

Inclusion Criteria:

- Patients who have Type 2 Diabetes Mellitus, with suboptimal glucose control, while either not on AHA (antihyperglycemic agent) therapy or on monotherapy or on low-dose combination therapy

Exclusion Criteria:

- Patients have a history of Type 1 Diabetes Mellitus
- Patients taking insulin or thiazolidinedione (TZD, a peroxisome proliferator-activated receptor [PPAR]-gamma agonist)
- Patients who have a contraindication to metformin

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: NCT00479466

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: NCT00479466 History of Changes
Other Study ID Numbers: 0893-008 2007_526
Study First Received: May 25, 2007
Results First Received: October 7, 2011
Last Updated: September 8, 2015
Health Authority: United States: Food and Drug Administration

Additional relevant MeSH terms:

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

ClinicalTrials.gov processed this record on April 14, 2016

TO TOP

Dose-Range Finding Study for MK0893 (0893-008)

This study has been terminated.

(Sufficient data regarding the dose-response to MK-0893 had been obtained from the first cohort of the study to assess the safety and efficacy)

Sponsor:
Merck Sharp & Dohme Corp.

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

ClinicalTrials.gov Identifier:
NCT00479466

First received: May 25, 2007
Last updated: September 8, 2015
Last verified: September 2015
History of Changes

Results First Received: October 7, 2011

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: MK0893 Drug: Metformin Drug: Placebo to MK0893 Drug: Placebo to 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
Placebo	No text entered.
MK0893 20 mg	No text entered.
MK0893 40 mg	No text entered.
MK0893 60 mg	No text entered.
MK0893 80 mg	No text entered.
Metformin HCL	No text entered.

Participant Flow: Overall Study

	Placebo	MK0893 20 mg	MK0893 40 mg	MK0893 60 mg	MK0893 80 mg	Metformin HCL
STARTED	57	57	57	58	56	57
COMPLETED	44	49	54	55	48	53
NOT COMPLETED	13	8	3	3	8	4
Adverse Event	5	1	0	1	2	0
Hyperglycemia	0	0	0	0	0	1
Lack of Efficacy	2	0	1	0	0	0
Lost to Follow-up	0	1	1	0	2	2
Physician Decision	2	1	1	0	0	0
Pregnancy	0	0	0	0	1	0
Protocol Violation	1	0	0	0	0	0
Withdrawal by Subject	3	5	0	2	3	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	No text entered.
MK0893 20 mg	No text entered.
MK0893 40 mg	No text entered.
MK0893 60 mg	No text entered.
MK0893 80 mg	No text entered.
Metformin HCL	No text entered.
Total	Total of all reporting groups

Baseline Measures

	Placebo	MK0893 20 mg	MK0893 40 mg	MK0893 60 mg	MK0893 80 mg	Metformin HCL	Total
Number of Participants [units: participants]	**57**	**57**	**57**	**58**	**56**	**57**	**342**
Age [units: years] Mean (Standard Deviation)	**54.1 (10.2)**	**55.6 (8.2)**	**53.7 (8.2)**	**56.1 (7.9)**	**53.5 (10.4)**	**55.1 (8.2)**	**54.7 (8.9)**
Gender [units: participants]							
Female	**31**	**28**	**22**	**26**	**31**	**30**	**168**
Male	**26**	**29**	**35**	**32**	**25**	**27**	**174**

Outcome Measures

Hide All Outcome Measures

1. Primary: Change From Baseline to Week 12 in Fasting Plasma Glucose (FPG) [Time Frame: Week 12]

Measure Type	Primary
Measure Title	Change From Baseline to Week 12 in Fasting Plasma Glucose (FPG)
Measure Description	No text entered.
Time Frame	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.
All participants who received at least one dose of study therapy, had a baseline measurement, and had at least one post-randomization measurement.

Reporting Groups

	Description
Placebo	No text entered.
MK0893 20 mg	No text entered.
MK0893 40 mg	No text entered.
MK0893 60 mg	No text entered.
MK0893 80 mg	No text entered.
Metformin HCL	No text entered.

Measured Values

	Placebo	MK0893 20 mg	MK0893 40 mg	MK0893 60 mg	MK0893 80 mg	Metformin HCL
Number of Participants Analyzed [units: participants]	**54**	**55**	**57**	**57**	**54**	**57**
Change From Baseline to Week 12 in Fasting Plasma Glucose (FPG) [units: mg/dL] Least Squares Mean (95% Confidence Interval)	**-1.8 (-11.4 to 7.8)**	**-32.4 (-41.7 to -23.2)**	**-48.4 (-57.4 to -39.5)**	**-53.0 (-61.9 to -44.1)**	**-63.0 (-72.4 to -53.7)**	**-37.3 (-46.3 to -28.4)**

Statistical Analysis 1 for Change From Baseline to Week 12 in Fasting Plasma Glucose (FPG)

Groups [1]	Placebo vs. MK0893 20 mg
Method [2]	ANCOVA
P Value [3]	<0.001
Mean Difference (Final Values) [4]	-30.6
95% Confidence Interval	-44.0 to -17.3

[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.

Statistical Analysis 2 for Change From Baseline to Week 12 in Fasting Plasma Glucose (FPG)

Groups [1]	Placebo vs. MK0893 40 mg
Method [2]	ANCOVA
P Value [3]	<0.001
Mean Difference (Final Values) [4]	-46.6
95% Confidence Interval	-59.7 to -33.4

[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.

Statistical Analysis 3 for Change From Baseline to Week 12 in Fasting Plasma Glucose (FPG)

Groups [1]	Placebo vs. MK0893 60 mg
Method [2]	ANCOVA
P Value [3]	<0.001
Mean Difference (Final Values) [4]	-51.1
95% Confidence Interval	-64.3 to -38.0

[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.

Statistical Analysis 4 for Change From Baseline to Week 12 in Fasting Plasma Glucose (FPG)

Groups [1]	Placebo vs. MK0893 80 mg
Method [2]	ANCOVA
P Value [3]	<0.001
Mean Difference (Final Values) [4]	-61.2
95% Confidence Interval	

	-74.6 to -47.8

[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.

Statistical Analysis 5 for Change From Baseline to Week 12 in Fasting Plasma Glucose (FPG)

Groups [1]	Placebo vs. Metformin HCL
Method [2]	ANCOVA
P Value [3]	<0.001
Mean Difference (Final Values) [4]	-35.5
95% Confidence Interval	-48.6 to -22.4

[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. Secondary: Change From Baseline to Week 12 in Hemoglobin A1c (HbA1c) [Time Frame: Week 12]

Measure Type	Secondary
Measure Title	Change From Baseline to Week 12 in Hemoglobin A1c (HbA1c)
Measure Description	No text entered.
Time Frame	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.

All participants who received at least one dose of study therapy, had a baseline measurement, and had at least one post-randomization measurement.

Reporting Groups

	Description
Placebo	No text entered.
MK0893 20 mg	No text entered.
MK0893 40 mg	No text entered.
MK0893 60 mg	No text entered.
MK0893 80 mg	No text entered.
Metformin HCL	No text entered.

Measured Values

	Placebo	MK0893 20 mg	MK0893 40 mg	MK0893 60 mg	MK0893 80 mg	Metformin HCL
Number of Participants Analyzed [units: participants]	**48**	**51**	**57**	**57**	**52**	**56**
Change From Baseline to Week 12 in Hemoglobin A1c (HbA1c) [units: mg/dL] Least Squares Mean (95% Confidence Interval)	**0.54 (0.27 to 0.82)**	**-0.60 (-0.87 to -0.33)**	**-0.99 (-1.25 to -0.73)**	**-1.14 (-1.40 to -0.89)**	**-1.52 (-1.79 to -1.25)**	**-0.78 (-1.04 to -0.52)**

Statistical Analysis 1 for Change From Baseline to Week 12 in Hemoglobin A1c (HbA1c)

Groups [1]	Placebo vs. MK0893 20 mg
Method [2]	ANCOVA
P Value [3]	<0.001
Mean Difference (Final Values) [4]	-1.15
95% Confidence Interval	-1.53 to -0.76

[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.

Statistical Analysis 2 for Change From Baseline to Week 12 in Hemoglobin A1c (HbA1c)

Groups [1]	Placebo vs. MK0893 40 mg
Method [2]	ANCOVA
P Value [3]	<0.001
Mean Difference (Final Values) [4]	-1.53
95% Confidence Interval	-1.91 to -1.15

[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.

Statistical Analysis 3 for Change From Baseline to Week 12 in Hemoglobin A1c (HbA1c)

Groups [1]	Placebo vs. MK0893 60 mg
Method [2]	ANCOVA
P Value [3]	<0.001
Mean Difference (Final Values) [4]	-1.69
95% Confidence Interval	-2.07 to -1.31

[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.

Statistical Analysis 4 for Change From Baseline to Week 12 in Hemoglobin A1c (HbA1c)

Groups [1]	Placebo vs. MK0893 80 mg
Method [2]	ANCOVA

P Value [3]	<0.001
Mean Difference (Final Values) [4]	-2.06
95% Confidence Interval	-2.45 to -1.68

[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.

Statistical Analysis 5 for Change From Baseline to Week 12 in Hemoglobin A1c (HbA1c)

Groups [1]	Placebo vs. Metformin HCL
Method [2]	ANCOVA
P Value [3]	<0.001
Mean Difference (Final Values) [4]	-1.32
95% Confidence Interval	-1.70 to -0.95

[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.

3. Secondary: Change From Baseline to Week 12 in 2-Hour Post Prandial Glucose (PPG) [Time Frame: Week 12]

Measure Type	Secondary
Measure Title	Change From Baseline to Week 12 in 2-Hour Post Prandial Glucose (PPG)
Measure Description	No text entered.
Time Frame	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.
All participants who received at least one dose of study therapy, had a baseline measurement, and had at least one post-randomization measurement.

Reporting Groups

	Description
Placebo	No text entered.
MK0893 20 mg	No text entered.
MK0893 40 mg	No text entered.
MK0893 60 mg	No text entered.
MK0893 80 mg	No text entered.
Metformin HCL	No text entered.

Measured Values

	Placebo	MK0893 20 mg	MK0893 40 mg	MK0893 60 mg	MK0893 80 mg	Metformin HCL
Number of Participants Analyzed [units: participants]	**41**	**47**	**55**	**54**	**47**	**53**
Change From Baseline to Week 12 in 2-Hour Post Prandial Glucose (PPG) [units: mg/dL] Least Squares Mean (95% Confidence Interval)	**-8.1 (-24.6 to 8.4)**	**-64.9 (-80.3 to -49.5)**	**-78.1 (-92.4 to -63.8)**	**-95.5 (-110.0 to -80.9)**	**-109.7 (-125.1 to -94.3)**	**-68.9 (-83.4 to -54.3)**

Statistical Analysis 1 for Change From Baseline to Week 12 in 2-Hour Post Prandial Glucose (PPG)

Groups [1]	Placebo vs. MK0893 20 mg
Method [2]	ANCOVA
P Value [3]	<0.001
Mean Difference (Final Values) [4]	-56.8
95% Confidence Interval	-79.4 to -34.3

[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.

Statistical Analysis 2 for Change From Baseline to Week 12 in 2-Hour Post Prandial Glucose (PPG)

Groups [1]	Placebo vs. MK0893 40 mg
Method [2]	ANCOVA
P Value [3]	<0.001
Mean Difference (Final Values) [4]	-70.0
95% Confidence Interval	-91.8 to -48.2

[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.

Statistical Analysis 3 for Change From Baseline to Week 12 in 2-Hour Post Prandial Glucose (PPG)

Groups [1]	Placebo vs. MK0893 60 mg
Method [2]	ANCOVA
P Value [3]	<0.001
Mean Difference (Final Values) [4]	-87.4
95% Confidence Interval	-109.4 to -65.3

[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.

Statistical Analysis 4 for Change From Baseline to Week 12 in 2-Hour Post Prandial Glucose (PPG)

Groups [1]	Placebo vs. MK0893 80 mg
Method [2]	ANCOVA
P Value [3]	<0.001
Mean Difference (Final Values) [4]	-101.6
95% Confidence Interval	-124.2 to -79.1

[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.

Statistical Analysis 5 for Change From Baseline to Week 12 in 2-Hour Post Prandial Glucose (PPG)

Groups [1]	Placebo vs. Metformin HCL
Method [2]	ANCOVA
P Value [3]	<0.001
Mean Difference (Final Values) [4]	-60.8
95% Confidence Interval	-82.7 to -38.8

[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.

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	No text entered.

Additional Description	No text entered.

Reporting Groups

	Description
Placebo	No text entered.
MK0893 20 mg	No text entered.
MK0893 40 mg	No text entered.
MK0893 60 mg	No text entered.
MK0893 80 mg	No text entered.
Metformin HCL	No text entered.

Serious Adverse Events

	Placebo	MK0893 20 mg	MK0893 40 mg	MK0893 60 mg	MK0893 80 mg	Metformin HCL
Total, serious adverse events						
# participants affected / at risk	**5/57 (8.77%)**	**0/57 (0.00%)**	**1/57 (1.75%)**	**0/58 (0.00%)**	**2/56 (3.57%)**	**0/57 (0.00%)**
Cardiac disorders						
Angina unstable [1]						
# participants affected / at risk	**0/57 (0.00%)**	**0/57 (0.00%)**	**1/57 (1.75%)**	**0/58 (0.00%)**	**0/56 (0.00%)**	**0/57 (0.00%)**
# events	**0**	**0**	**1**	**0**	**0**	**0**
Gastrointestinal disorders						
Inguinal hernia [1]						
# participants affected / at risk	**1/57 (1.75%)**	**0/57 (0.00%)**	**0/57 (0.00%)**	**0/58 (0.00%)**	**0/56 (0.00%)**	**0/57 (0.00%)**
# events	**1**	**0**	**0**	**0**	**0**	**0**
General disorders						
Chest pain [1]						
# participants affected / at risk	**2/57 (3.51%)**	**0/57 (0.00%)**	**0/57 (0.00%)**	**0/58 (0.00%)**	**0/56 (0.00%)**	**0/57 (0.00%)**
# events	**2**	**0**	**0**	**0**	**0**	**0**
Infections and infestations						
Pulmonary tuberculosis [1]						
# participants affected / at risk	**1/57 (1.75%)**	**0/57 (0.00%)**	**0/57 (0.00%)**	**0/58 (0.00%)**	**0/56 (0.00%)**	**0/57 (0.00%)**

# events	1	0	0	0	0	0
Investigations						
Blood bilirubin increased [1]						
# participants affected / at risk	1/57 (1.75%)	0/57 (0.00%)	0/57 (0.00%)	0/58 (0.00%)	0/56 (0.00%)	0/57 (0.00%)
# events	1	0	0	0	0	0
Nervous system disorders						
Cerebral haemorrhage [1]						
# participants affected / at risk	0/57 (0.00%)	0/57 (0.00%)	0/57 (0.00%)	0/58 (0.00%)	1/56 (1.79%)	0/57 (0.00%)
# events	0	0	0	0	1	0
Pregnancy, puerperium and perinatal conditions						
Abortion spontaneous [1]						
# participants affected / at risk	0/57 (0.00%)	0/57 (0.00%)	0/57 (0.00%)	0/58 (0.00%)	1/56 (1.79%)	0/57 (0.00%)
# events	0	0	0	0	1	0

1 Term from vocabulary, MedDRA 12.0

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	5.0%

Reporting Groups

	Description
Placebo	No text entered.
MK0893 20 mg	No text entered.
MK0893 40 mg	No text entered.
MK0893 60 mg	No text entered.
MK0893 80 mg	No text entered.
Metformin HCL	No text

	entered.

Other Adverse Events

	Placebo	MK0893 20 mg	MK0893 40 mg	MK0893 60 mg	MK0893 80 mg	Metformin HCL
Total, other (not including serious) adverse events						
# participants affected / at risk	**16/57 (28.07%)**	**11/57 (19.30%)**	**22/57 (38.60%)**	**16/58 (27.59%)**	**12/56 (21.43%)**	**13/57 (22.81%)**
Gastrointestinal disorders						
Abdominal pain upper [1]						
# participants affected / at risk	**0/57 (0.00%)**	**1/57 (1.75%)**	**3/57 (5.26%)**	**0/58 (0.00%)**	**0/56 (0.00%)**	**1/57 (1.75%)**
# events	**0**	**1**	**3**	**0**	**0**	**1**
Diarrhoea [1]						
# participants affected / at risk	**2/57 (3.51%)**	**1/57 (1.75%)**	**2/57 (3.51%)**	**2/58 (3.45%)**	**1/56 (1.79%)**	**4/57 (7.02%)**
# events	**4**	**1**	**2**	**2**	**1**	**4**
Nausea [1]						
# participants affected / at risk	**1/57 (1.75%)**	**0/57 (0.00%)**	**3/57 (5.26%)**	**3/58 (5.17%)**	**1/56 (1.79%)**	**4/57 (7.02%)**
# events	**1**	**0**	**3**	**3**	**1**	**9**
Infections and infestations						
Influenza [1]						
# participants affected / at risk	**2/57 (3.51%)**	**2/57 (3.51%)**	**3/57 (5.26%)**	**1/58 (1.72%)**	**1/56 (1.79%)**	**1/57 (1.75%)**
# events	**2**	**2**	**3**	**1**	**1**	**1**
Nasopharyngitis [1]						
# participants affected / at risk	**3/57 (5.26%)**	**1/57 (1.75%)**	**4/57 (7.02%)**	**3/58 (5.17%)**	**3/56 (5.36%)**	**1/57 (1.75%)**
# events	**3**	**1**	**4**	**3**	**3**	**1**
Upper respiratory tract infection [1]						
# participants affected / at risk	**1/57 (1.75%)**	**2/57 (3.51%)**	**2/57 (3.51%)**	**3/58 (5.17%)**	**3/56 (5.36%)**	**2/57 (3.51%)**
# events	**1**	**2**	**2**	**3**	**3**	**2**
Injury, poisoning and procedural complications						
Accidental overdose [1]						
# participants affected / at risk	**2/57 (3.51%)**	**2/57 (3.51%)**	**0/57 (0.00%)**	**4/58 (6.90%)**	**1/56 (1.79%)**	**0/57 (0.00%)**
# events	**3**	**2**	**0**	**4**	**1**	**0**
Metabolism and nutrition disorders						
Hyperglycaemia [1]						
# participants affected / at risk	**4/57 (7.02%)**	**0/57 (0.00%)**	**2/57 (3.51%)**	**0/58 (0.00%)**	**1/56 (1.79%)**	**0/57 (0.00%)**
# events	**4**	**0**	**2**	**0**	**1**	**0**
Musculoskeletal and connective tissue disorders						
Arthralgia [1]						
# participants affected / at risk	**2/57 (3.51%)**	**2/57 (3.51%)**	**0/57 (0.00%)**	**2/58 (3.45%)**	**0/56 (0.00%)**	**3/57 (5.26%)**
# events	**2**	**2**	**0**	**2**	**0**	**4**
Pain in extremity [1]						

# participants affected / at risk	0/57 (0.00%)	0/57 (0.00%)	2/57 (3.51%)	3/58 (5.17%)	0/56 (0.00%)	0/57 (0.00%)
# events	0	0	2	3	0	0
Nervous system disorders						
Dizziness [1]						
# participants affected / at risk	1/57 (1.75%)	3/57 (5.26%)	2/57 (3.51%)	0/58 (0.00%)	0/56 (0.00%)	2/57 (3.51%)
# events	1	4	2	0	0	2
Headache [1]						
# participants affected / at risk	5/57 (8.77%)	1/57 (1.75%)	4/57 (7.02%)	5/58 (8.62%)	1/56 (1.79%)	4/57 (7.02%)
# events	6	1	5	7	1	4
Respiratory, thoracic and mediastinal disorders						
Cough [1]						
# participants affected / at risk	1/57 (1.75%)	0/57 (0.00%)	4/57 (7.02%)	0/58 (0.00%)	0/56 (0.00%)	0/57 (0.00%)
# events	1	0	4	0	0	0

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

Sufficient data regarding the dose-response to MK-0893 had been obtained from the first cohort of the study to assess the safety and efficacy, thus the study was discontinued.

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.

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:	NCT00479466 History of Changes
Other Study ID Numbers:	0893-008 2007_526
Study First Received:	May 25, 2007
Results First Received:	October 7, 2011
Last Updated:	September 8, 2015
Health Authority:	United States: Food and Drug Administration

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