An Investigational Drug Study in Patients With Type 2 Diabetes Mellitus (MK0431-023)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

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

ClinicalTrials.gov Identifier:
NCT00094757

First received: October 22, 2004
Last updated: April 27, 2015
Last verified: April 2015
History of Changes

Purpose

The purpose of this study is to determine the safety and effectiveness of an investigational drug in patients with Type 2 Diabetes Mellitus.

Condition	Intervention	Phase
Diabetes Mellitus, Type 2	Drug: Comparator: sitagliptin 100 mg Drug: Comparator: sitagliptin 200 mg Drug: Comparator: placebo Drug: Comparator: pioglitazone	Phase 3

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, Randomized, Double-Blind Study of MK0431 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: Pioglitazone Pioglitazone hydrochloride Sitagliptin Sitagliptin phosphate

U.S. FDA Resources

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

Primary Outcome Measures:

- Change From Baseline in A1C at Week 18 [Time Frame: Weeks 0-18] [Designated as safety issue: No]

  Hemoglobin A1C (A1C) is measured as percent. Thus this change from baseline reflects the Week 18 A1C percent minus the Week 0 A1C percent.

Secondary Outcome Measures:

- Change From Baseline in FPG at Week 18 [Time Frame: Weeks 0-18] [Designated as safety issue: No]

  The change from baseline reflects the Week 18 Fasting Plasma Glucose (FPG) minus the Week 0 FPG.

- Change From Baseline in A1C at Week 54 [Time Frame: Weeks 0-54] [Designated as safety issue: No]

  A1C is measured as percent. Thus this change from baseline reflects the Week 54 A1C percent minus the Week 0 A1C percent.

- Change From Baseline in FPG at Week 54 [Time Frame: Weeks 0-54] [Designated as safety issue: No]

  The change from baseline reflects the Week 54 FPG minus the Week 0 FPG.

Enrollment:	521
Study Start Date:	October 2004
Study Completion Date:	April 2006
Primary Completion Date:	August 2005 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: Sitagliptin 100 mg Sitagliptin 100 mg	Drug: Comparator: sitagliptin 100 mg sitagliptin 100 mg oral tablet once daily for 54 weeks
Experimental: Sitagliptin 200 mg Sitagliptin 200 mg	Drug: Comparator: sitagliptin 200 mg sitagliptin 200 mg (2- 100 mg oral tablets) once daily for 54 weeks
Placebo Comparator: Placebo/Pioglitazone Placebo/Pioglitazone	Drug: Comparator: placebo placebo oral tablet once daily during Phase A (Weeks 0-18) Drug: Comparator: pioglitazone pioglitazone 30 mg oral tablet once daily during Phase B (Weeks 18-54)

Eligibility

Ages Eligible for Study:	18 Years to 75 Years
Genders Eligible for Study:	Both
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- Patients at least 18 years of age and not older than 75 who have a specific type of diabetes called Type 2 Diabetes Mellitus

Exclusion Criteria:

- Younger than 18 years of age or older than 75
- Any condition, which in the opinion of the investigator, may not be in the patient's best interest to participate

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: NCT00094757

Sponsors and Collaborators

Merck Sharp & Dohme Corp.

Investigators

Study Director: Medical Monitor Merck Sharp & Dohme Corp.

More Information

Additional Information:

MedWatch - FDA maintained medical product safety Information EXIT

Merck: Patient & Caregiver U.S. Product Web Site EXIT

Publications:

Raz I, Hanefeld M, Xu L, Caria C, Williams-Herman D, Khatami H; Sitagliptin Study 023 Group. Efficacy and safety of the dipeptidyl peptidase-4 inhibitor sitagliptin as monotherapy in patients with type 2 diabetes mellitus. Diabetologia. 2006 Nov;49(11):2564-71. Epub 2006 Sep 26.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00094757 History of Changes
Other Study ID Numbers:	0431-023 2004_045
Study First Received:	October 22, 2004
Results First Received:	June 22, 2010
Last Updated:	April 27, 2015
Health Authority:	United States: Food and Drug Administration

Additional relevant MeSH terms:

Diabetes Mellitus	Hormones
Diabetes Mellitus, Type 2	Hormones, Hormone Substitutes, and Hormone Antagonists
Endocrine System Diseases	Hypoglycemic Agents
Glucose Metabolism Disorders	Incretins
Metabolic Diseases	Molecular Mechanisms of Pharmacological Action
Pioglitazone	Pharmacologic Actions
Sitagliptin	Physiological Effects of Drugs
Dipeptidyl-Peptidase IV Inhibitors	Protease Inhibitors
Enzyme Inhibitors	

ClinicalTrials.gov processed this record on April 13, 2016

TO TOP

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

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

An Investigational Drug Study in Patients With Type 2 Diabetes Mellitus (MK0431-023)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

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

ClinicalTrials.gov Identifier:
NCT00094757

First received: October 22, 2004
Last updated: April 27, 2015
Last verified: April 2015
History of Changes

Results First Received: June 22, 2010

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Investigator); Primary Purpose: Treatment
Condition:	Diabetes Mellitus, Type 2
Interventions:	Drug: Comparator: sitagliptin 100 mg Drug: Comparator: sitagliptin 200 mg Drug: Comparator: placebo Drug: Comparator: pioglitazone

Participant Flow

Hide Participant Flow

Recruitment Details

Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations

First Patient In: 15-Oct-2004. Last Patient Last Visit: 28-Apr-2006. 60 medical clinics in the United States (US), 37 in 4 countries in Europe, and 17 in 5 countries in the rest of the world.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment

Patients 18-75 years of age with type 2 diabetes mellitus (T2DM) with inadequate glycemic control (Hemoglobin A1C ≥7% and ≤10.0%) on diet and exercise alone were eligible to enter the study.

Reporting Groups

	Description
Sitagliptin 100 mg	The Sitagliptin 100 mg got 1 sitagliptin 100 mg tablet and 1 sitagliptin matching placebo tablet once daily Weeks 0-54 and pioglitazone placebo once daily in Weeks 18-54.
Sitagliptin 200 mg	The Sitagliptin 200 mg got 2 sitagliptin 100 mg tablets once daily Weeks 0-54 and pioglitazone placebo once daily in Weeks 18-54.
Placebo/Pioglitazone	The Placebo/Pioglitazone got 2 sitagliptin matching placebo tablets once daily in Weeks 0- 54 and pioglitazone 30 mg/day once daily in Weeks 18-54.

Participant Flow: Overall Study

	Sitagliptin 100 mg	Sitagliptin 200 mg	Placebo/Pioglitazone
STARTED	**205**	**206**	**110**
COMPLETED	**152**	**144**	**80**
NOT COMPLETED	**53**	**62**	**30**
Adverse Event	**11**	**9**	**6**
Lack of Efficacy	**11**	**15**	**8**
Lost to Follow-up	**3**	**5**	**6**
Patient Moved	**2**	**1**	**1**
Protocol Violation	**8**	**5**	**3**
Withdrawal by Subject	**14**	**21**	**5**
Unspecified	**3**	**3**	**1**
Protocol specified discontinuation	**1**	**3**	**0**

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
Sitagliptin 100 mg	The Sitagliptin 100 mg got 1 sitagliptin 100 mg tablet and 1 sitagliptin matching placebo tablet once daily Weeks 0-54 and pioglitazone placebo once daily in Weeks 18-54.
Sitagliptin 200 mg	The Sitagliptin 200 mg got 2 sitagliptin 100 mg tablets once daily Weeks 0-54 and pioglitazone placebo once daily in Weeks 18-54.
Placebo/Pioglitazone	The Placebo/Pioglitazone got 2 sitagliptin matching placebo tablets once daily in Weeks 0- 54 and pioglitazone 30 mg/day once daily in Weeks 18-54.
Total	Total of all reporting groups

Baseline Measures

	Sitagliptin 100 mg	Sitagliptin 200 mg	Placebo/Pioglitazone	Total
Number of Participants [units: participants]	205	206	110	521
Age [units: years] Mean (Standard Deviation)	54.5 (10.0)	55.4 (9.2)	55.5 (10.1)	55.1 (9.7)
Gender [units: participants]				
Female	95	102	41	238
Male	110	104	69	283
Race/Ethnicity, Customized [units: participants]				
White	142	146	68	356
Black	16	11	12	39
Hispanic	37	39	22	98
Asian	8	7	5	20
Other	2	3	3	8
Hemoglobin A1C (A1C) [units: Percent] Mean (Standard Deviation)	8.0 (0.8)	8.1 (0.9)	8.0 (0.9)	8.1 (0.9)

Outcome Measures

Hide All Outcome Measures

1. Primary: Change From Baseline in A1C at Week 18 [Time Frame: Weeks 0-18]

Measure Type	Primary
Measure Title	Change From Baseline in A1C at Week 18
Measure Description	Hemoglobin A1C (A1C) is measured as percent. Thus this change from baseline reflects the Week 18 A1C percent minus the Week 0 A1C percent.
Time Frame	Weeks 0-18
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 Patients Treated included those with ≥1 dose of study therapy, had a baseline and ≥1 post-baseline value. For those with no data at Week 18, last post-baseline observation was carried forward. Data after initiation of glycemic rescue were considered missing. Analysis adjusted for baseline values and prior antihyperglycemic therapy status.

Reporting Groups

	Description

Sitagliptin 100 mg	The Sitagliptin 100 mg got 1 sitagliptin 100 mg tablet and 1 sitagliptin matching placebo tablet once daily Weeks 0-54 and pioglitazone placebo once daily in Weeks 18-54.
Sitagliptin 200 mg	The Sitagliptin 200 mg got 2 sitagliptin 100 mg tablets once daily Weeks 0-54 and pioglitazone placebo once daily in Weeks 18-54.
Placebo/Pioglitazone	The Placebo/Pioglitazone got 2 sitagliptin matching placebo tablets once daily in Weeks 0- 54 and pioglitazone 30 mg/day once daily in Weeks 18-54.

Measured Values

	Sitagliptin 100 mg	Sitagliptin 200 mg	Placebo/Pioglitazone
Number of Participants Analyzed [units: participants]	**193**	**199**	**103**
Change From Baseline in A1C at Week 18 [units: percent] Least Squares Mean (95% Confidence Interval)	**-0.48 (-0.61 to -0.35)**	**-0.36 (-0.48 to -0.23)**	**0.12 (-0.05 to 0.30)**

Statistical Analysis 1 for Change From Baseline in A1C at Week 18

Groups [1]	Sitagliptin 100 mg vs. Placebo/Pioglitazone
Method [2]	ANCOVA
P Value [3]	<0.001
Mean Difference (Net) [4]	-0.60
Standard Deviation	(0.90)
95% Confidence Interval	-0.82 to -0.39

[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:
	Model terms: treatment, baseline, prior anti-hyperglycemic therapy status (on vs. not on prior therapy)
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 2 for Change From Baseline in A1C at Week 18

Groups [1]	Sitagliptin 200 mg vs. Placebo/Pioglitazone
Method [2]	ANCOVA
P Value [3]	<0.001
Mean Difference (Net) [4]	-0.48
Standard Deviation	(0.90)
95% Confidence Interval	-0.70 to -0.26

[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:
	Model terms: treatment, baseline, prior anti-hyperglycemic therapy status (on vs. not on prior therapy)
[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 in FPG at Week 18 [Time Frame: Weeks 0-18]

Measure Type	Secondary
Measure Title	Change From Baseline in FPG at Week 18
Measure Description	The change from baseline reflects the Week 18 Fasting Plasma Glucose (FPG) minus the Week 0 FPG.
Time Frame	Weeks 0-18
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 Patients Treated included patients who received at least 1 dose of study therapy, and had a baseline value and ≥1 post-baseline value for this outcome. The last post-baseline observed measurement was carried forward to Week 18 for patients with no data at Week 18. Data after initiation of glycemic rescue were considered missing.

Reporting Groups

	Description
Sitagliptin 100 mg	The Sitagliptin 100 mg got 1 sitagliptin 100 mg tablet and 1 sitagliptin matching placebo tablet once daily Weeks 0-54 and pioglitazone placebo once daily in Weeks 18-54.
Sitagliptin 200 mg	The Sitagliptin 200 mg got 2 sitagliptin 100 mg tablets once daily Weeks 0-54 and pioglitazone placebo once daily in Weeks 18-54.
Placebo/Pioglitazone	The Placebo/Pioglitazone got 2 sitagliptin matching placebo tablets once daily in Weeks 0- 54 and pioglitazone 30 mg/day once daily in Weeks 18-54.

Measured Values

	Sitagliptin 100 mg	**Sitagliptin 200 mg**	**Placebo/Pioglitazone**
Number of Participants Analyzed [units: participants]	**201**	**202**	**107**
Change From Baseline in FPG at Week 18 [units: mg/dL] Least Squares Mean (95% Confidence Interval)	**-12.7 (-19.1 to -6.3)**	**-9.9 (-16.2 to -3.5)**	**7.0 (-1.8 to 15.8)**

Statistical Analysis 1 for Change From Baseline in FPG at Week 18

Groups [1]	Sitagliptin 100 mg vs. Placebo/Pioglitazone
Method [2]	ANCOVA
P Value [3]	<0.001
Mean Difference (Net) [4]	-19.7
Standard Deviation	(45.9)
95% Confidence Interval	-30.5 to -8.9

[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:
	Model terms: treatment, baseline, prior anti-hyperglycemic therapy status
[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 in FPG at Week 18

Groups [1]	Sitagliptin 200 mg vs. Placebo/Pioglitazone
Method [2]	ANCOVA
P Value [3]	<0.002
Mean Difference (Net) [4]	-16.9
Standard Deviation	(45.9)
95% Confidence Interval	-27.6 to -6.1

[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:
	Model terms: treatment, baseline, prior anti-hyperglycemic therapy status
[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 in A1C at Week 54 [Time Frame: Weeks 0-54]

Measure Type	Secondary
Measure Title	Change From Baseline in A1C at Week 54
Measure Description	A1C is measured as percent. Thus this change from baseline reflects the Week 54 A1C percent minus the Week 0 A1C percent.
Time Frame	Weeks 0-54
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 Patients Treated included patients who received at least 1 dose of study therapy post-Week 18, a baseline value and ≥1 post-Week 18 value for this outcome. The last post- Week 18 observed measurement was carried forward to Week 54 for patients with no data at Week 54. Data after initiation of glycemic rescue were considered missing.

Reporting Groups

	Description
Sitagliptin 100 mg	The Sitagliptin 100 mg got 1 sitagliptin 100 mg tablet and 1 sitagliptin matching placebo tablet once daily Weeks 0-54 and pioglitazone placebo once daily in Weeks 18-54.
Sitagliptin 200 mg	The Sitagliptin 200 mg got 2 sitagliptin 100 mg tablets once daily Weeks 0-54 and pioglitazone placebo once daily in Weeks 18-54.
Placebo/Pioglitazone	The Placebo/Pioglitazone got 2 sitagliptin matching placebo tablets once daily in Weeks 0- 54 and pioglitazone 30 mg/day once daily in Weeks 18-54.

Measured Values

	Sitagliptin 100 mg	**Sitagliptin 200 mg**	**Placebo/Pioglitazone**
Number of Participants Analyzed [units: participants]	**156**	**158**	**68**
Change From Baseline in A1C at Week 54 [units: percent] Least Squares Mean (95% Confidence Interval)	**-0.28 (-0.42 to -0.14)**	**-0.19 (-0.33 to -0.05)**	**-0.87 (-1.08 to -0.66)**

No statistical analysis provided for Change From Baseline in A1C at Week 54

4. Secondary: Change From Baseline in FPG at Week 54 [Time Frame: Weeks 0-54]

Measure Type	Secondary
Measure Title	Change From Baseline in FPG at Week 54
Measure Description	The change from baseline reflects the Week 54 FPG minus the Week 0 FPG.
Time Frame	Weeks 0-54
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 Patients Treated included patients who received at least 1 dose of study therapy 1 post-Week 18, a baseline value and ≥1 post-Week 18 value for this outcome. The last post- Week 18 observed measurement was carried forward to Week 54 for patients with no data at Week 54. Data after initiation of glycemic rescue were considered missing.

Reporting Groups

	Description
Sitagliptin 100 mg	The Sitagliptin 100 mg got 1 sitagliptin 100 mg tablet and 1 sitagliptin matching placebo tablet once daily Weeks 0-54 and pioglitazone placebo once daily in Weeks 18-54.
Sitagliptin 200 mg	The Sitagliptin 200 mg got 2 sitagliptin 100 mg tablets once daily Weeks 0-54 and pioglitazone placebo once daily in Weeks 18-54.
Placebo/Pioglitazone	The Placebo/Pioglitazone got 2 sitagliptin matching placebo tablets once daily in Weeks 0- 54 and pioglitazone 30 mg/day once daily in Weeks 18-54.

Measured Values

	Sitagliptin 100 mg	Sitagliptin 200 mg	Placebo/Pioglitazone
Number of Participants Analyzed [units: participants]	**159**	**160**	**70**
Change From Baseline in FPG at Week 54 [units: mg/dL] Least Squares Mean (95% Confidence Interval)	**-5.5 (-11.5 to 0.5)**	**-0.7 (-6.7 to 5.3)**	**-28.0 (-37.1 to -18.9)**

No statistical analysis provided for Change From Baseline in FPG at Week 54

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	Weeks 0 to 54
Additional Description	Patients received rescue medication if they met specific glycemic goals. SAEs include events that occurred either before or after receiving rescue medication. Other AEs only includes those AEs that occurred prior to a patient receiving rescue medication.

Reporting Groups

	Description
Sitagliptin 100 mg	The Sitagliptin 100 mg got 1 sitagliptin 100 mg tablet and 1 sitagliptin matching placebo tablet once daily Weeks 0-54 and pioglitazone placebo once daily in Weeks 18-54.
Sitagliptin 200 mg	The Sitagliptin 200 mg got 2 sitagliptin 100 mg tablets once daily Weeks 0-54 and pioglitazone placebo once daily in Weeks 18-54.
Placebo/Pioglitazone	The Placebo/Pioglitazone got 2 sitagliptin matching placebo tablets once daily in Weeks 0- 54 and pioglitazone 30 mg/day once daily in Weeks 18-54.

Serious Adverse Events

	Sitagliptin 100 mg	Sitagliptin 200 mg	Placebo/Pioglitazone

Total, serious adverse events			
# participants affected / at risk	**15/205 (7.32%)**	**12/206 (5.83%)**	**10/110 (9.09%)**
Blood and lymphatic system disorders			
Anaemia [*1]			
# participants affected / at risk	**1/205 (0.49%)**	**0/206 (0.00%)**	**0/110 (0.00%)**
Cardiac disorders			
Angina Pectoris [*1]			
# participants affected / at risk	**1/205 (0.49%)**	**0/206 (0.00%)**	**0/110 (0.00%)**
Angina Unstable [*1]			
# participants affected / at risk	**1/205 (0.49%)**	**0/206 (0.00%)**	**0/110 (0.00%)**
Arteriosclerosis Coronary Artery [*1]			
# participants affected / at risk	**1/205 (0.49%)**	**1/206 (0.49%)**	**0/110 (0.00%)**
Atrial Flutter [*1]			
# participants affected / at risk	**0/205 (0.00%)**	**0/206 (0.00%)**	**1/110 (0.91%)**
Atrioventricular Block Complete [*1]			
# participants affected / at risk	**1/205 (0.49%)**	**0/206 (0.00%)**	**0/110 (0.00%)**
Coronary Artery Disease [*1]			
# participants affected / at risk	**0/205 (0.00%)**	**1/206 (0.49%)**	**1/110 (0.91%)**
Myocardial Infarction [*1]			
# participants affected / at risk	**2/205 (0.98%)**	**0/206 (0.00%)**	**0/110 (0.00%)**
Ventricular Extrasystoles [*1]			
# participants affected / at risk	**0/205 (0.00%)**	**1/206 (0.49%)**	**0/110 (0.00%)**
Eye disorders			
Cataract [*1]			
# participants affected / at risk	**0/205 (0.00%)**	**1/206 (0.49%)**	**0/110 (0.00%)**
Gastrointestinal disorders			
Diarrhoea [*1]			
# participants affected / at risk	**0/205 (0.00%)**	**0/206 (0.00%)**	**1/110 (0.91%)**
Gastrooesophageal Reflux Disease [*1]			
# participants affected / at risk	**0/205 (0.00%)**	**0/206 (0.00%)**	**1/110 (0.91%)**
Intestinal Obstruction [*1]			
# participants affected / at risk	**0/205 (0.00%)**	**1/206 (0.49%)**	**0/110 (0.00%)**
Pancreatitis Acute [*1]			
# participants affected / at risk	**0/205 (0.00%)**	**0/206 (0.00%)**	**1/110 (0.91%)**
Proctitis [*1]			
# participants affected / at risk	**0/205 (0.00%)**	**1/206 (0.49%)**	**0/110 (0.00%)**
Hepatobiliary disorders			
Cholelithiasis [*1]			
# participants affected / at risk	**1/205 (0.49%)**	**0/206 (0.00%)**	**0/110 (0.00%)**
Infections and infestations			
[*1]			

Appendicitis			
# participants affected / at risk	**1/205 (0.49%)**	**0/206 (0.00%)**	**0/110 (0.00%)**
Wound Infection [*1]			
# participants affected / at risk	**0/205 (0.00%)**	**0/206 (0.00%)**	**1/110 (0.91%)**
Injury, poisoning and procedural complications			
Complication Of Device Insertion [*1]			
# participants affected / at risk	**1/205 (0.49%)**	**0/206 (0.00%)**	**0/110 (0.00%)**
Polytraumatism [*1]			
# participants affected / at risk	**0/205 (0.00%)**	**1/206 (0.49%)**	**0/110 (0.00%)**
Investigations			
Blood Potassium Decreased [*1]			
# participants affected / at risk	**0/205 (0.00%)**	**1/206 (0.49%)**	**0/110 (0.00%)**
Blood Sodium Decreased [*1]			
# participants affected / at risk	**0/205 (0.00%)**	**1/206 (0.49%)**	**0/110 (0.00%)**
Musculoskeletal and connective tissue disorders			
Osteoarthritis [*1]			
# participants affected / at risk	**0/205 (0.00%)**	**1/206 (0.49%)**	**0/110 (0.00%)**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal Cell Carcinoma [*1]			
# participants affected / at risk	**0/205 (0.00%)**	**1/206 (0.49%)**	**0/110 (0.00%)**
Breast Cancer [*1]			
# participants affected / at risk	**1/205 (0.49%)**	**1/206 (0.49%)**	**0/110 (0.00%)**
Colon Cancer [*1]			
# participants affected / at risk	**0/205 (0.00%)**	**1/206 (0.49%)**	**0/110 (0.00%)**
Metastases To Bone [*1]			
# participants affected / at risk	**0/205 (0.00%)**	**0/206 (0.00%)**	**1/110 (0.91%)**
Pancreatic Carcinoma [*1]			
# participants affected / at risk	**0/205 (0.00%)**	**0/206 (0.00%)**	**1/110 (0.91%)**
Squamous Cell Carcinoma [*1]			
# participants affected / at risk	**1/205 (0.49%)**	**1/206 (0.49%)**	**0/110 (0.00%)**
Thyroid Adenoma [*1]			
# participants affected / at risk	**0/205 (0.00%)**	**0/206 (0.00%)**	**1/110 (0.91%)**
Thyroid Neoplasm [*1]			
# participants affected / at risk	**0/205 (0.00%)**	**0/206 (0.00%)**	**1/110 (0.91%)**
Uterine Cancer [*1]			
# participants affected / at risk	**0/205 (0.00%)**	**0/206 (0.00%)**	**1/110 (0.91%)**
Nervous system disorders			
Cerebrovascular Accident [*1]			
# participants affected / at risk	**1/205 (0.49%)**	**0/206 (0.00%)**	**0/110 (0.00%)**
Haemorrhagic Stroke [*1]			

# participants affected / at risk	1/205 (0.49%)	0/206 (0.00%)	0/110 (0.00%)
Syncope * 1			
# participants affected / at risk	1/205 (0.49%)	0/206 (0.00%)	1/110 (0.91%)
Vertebrobasilar Insufficiency * 1			
# participants affected / at risk	1/205 (0.49%)	0/206 (0.00%)	0/110 (0.00%)
Renal and urinary disorders			
Bladder Perforation * 1			
# participants affected / at risk	1/205 (0.49%)	0/206 (0.00%)	0/110 (0.00%)
Haematuria * 1			
# participants affected / at risk	1/205 (0.49%)	0/206 (0.00%)	0/110 (0.00%)
Reproductive system and breast disorders			
Benign Prostatic Hyperplasia * 1			
# participants affected / at risk	1/205 (0.49%)	0/206 (0.00%)	0/110 (0.00%)
Vascular disorders			
Leriche Syndrome * 1			
# participants affected / at risk	0/205 (0.00%)	1/206 (0.49%)	0/110 (0.00%)

* Events were collected by non-systematic assessment
1 Term from vocabulary, MedDRA (9.0)

Other Adverse Events

Hide Other Adverse Events

Time Frame	Weeks 0 to 54
Additional Description	Patients received rescue medication if they met specific glycemic goals. SAEs include events that occurred either before or after receiving rescue medication. Other AEs only includes those AEs that occurred prior to a patient receiving rescue medication.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Sitagliptin 100 mg	The Sitagliptin 100 mg got 1 sitagliptin 100 mg tablet and 1 sitagliptin matching placebo tablet once daily Weeks 0-54 and pioglitazone placebo once daily in Weeks 18-54.
Sitagliptin 200 mg	The Sitagliptin 200 mg got 2 sitagliptin 100 mg tablets once daily Weeks 0-54 and pioglitazone placebo once daily in Weeks 18-54.
Placebo/Pioglitazone	The Placebo/Pioglitazone got 2 sitagliptin matching placebo tablets once daily in Weeks 0- 54 and pioglitazone 30 mg/day once daily in Weeks 18-54.

Other Adverse Events

	Sitagliptin 100 mg	Sitagliptin 200 mg	Placebo/Pioglitazone
Total, other (not including serious) adverse events			

# participants affected / at risk	**70/205 (34.15%)**	**55/206 (26.70%)**	**37/110 (33.64%)**
Infections and infestations			
Influenza * 1			
# participants affected / at risk	**11/205 (5.37%)**	**8/206 (3.88%)**	**7/110 (6.36%)**
Upper Respiratory Tract Infection * 1			
# participants affected / at risk	**9/205 (4.39%)**	**14/206 (6.80%)**	**6/110 (5.45%)**
Urinary Tract Infection * 1			
# participants affected / at risk	**8/205 (3.90%)**	**10/206 (4.85%)**	**9/110 (8.18%)**
Investigations			
Blood Glucose Increased * 1			
# participants affected / at risk	**17/205 (8.29%)**	**7/206 (3.40%)**	**9/110 (8.18%)**
Glycosylated Haemoglobin Increased * 1			
# participants affected / at risk	**11/205 (5.37%)**	**2/206 (0.97%)**	**3/110 (2.73%)**
Musculoskeletal and connective tissue disorders			
Arthralgia * 1			
# participants affected / at risk	**5/205 (2.44%)**	**9/206 (4.37%)**	**6/110 (5.45%)**
Back Pain * 1			
# participants affected / at risk	**14/205 (6.83%)**	**11/206 (5.34%)**	**5/110 (4.55%)**
Nervous system disorders			
Headache * 1			
# participants affected / at risk	**13/205 (6.34%)**	**11/206 (5.34%)**	**5/110 (4.55%)**

* Events were collected by non-systematic assessment
1 Term from vocabulary, MedDRA (9.0)

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

Results Point of Contact:

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

Publications:

Raz I, Hanefeld M, Xu L, Caria C, Williams-Herman D, Khatami H; Sitagliptin Study 023 Group. Efficacy and safety of the dipeptidyl peptidase-4 inhibitor sitagliptin as monotherapy in patients with type 2 diabetes mellitus. Diabetologia. 2006 Nov;49(11):2564-71. Epub 2006 Sep 26.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00094757 History of Changes
Other Study ID Numbers:	0431-023 2004_045
Study First Received:	October 22, 2004
Results First Received:	June 22, 2010
Last Updated:	April 27, 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