Metformin Add-on Study in Patients With Type 2 Diabetes Mellitus (0431-020)(COMPLETED)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

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

ClinicalTrials.gov Identifier:
NCT00086515

First received: July 2, 2004
Last updated: April 27, 2015
Last verified: April 2015
History of Changes

Full Text View | Tabular View | Study Results | Disclaimer | How to Read a Study Record

Purpose

The purpose of this study is to determine the safety and efficacy of an investigational drug in patients with type 2 diabetes mellitus.

Condition	Intervention	Phase
Diabetes Mellitus, Type II	Drug: Sitagliptin (MK0431) Drug: Placebo/Glipizide 5 mg Drug: Metformin Drug: 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 to Evaluate the Safety and Efficacy of the Addition of MK0431 to Patients With Type 2 Diabetes Mellitus Who Have Inadequate Glycemic Control on Metformin Therapy

Resource links provided by NLM:

MedlinePlus related topics: Diabetes Type 2

Drug Information available for: Metformin Metformin hydrochloride Glipizide 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 Hemoglobin A1C (A1C) at Week 24 [Time Frame: Baseline and Week 24] [Designated as safety issue: No]

  A1C is measured as a percent. Thus, this change from baseline reflects the Week 24 A1C percent minus the Week 0 A1C percent.

Secondary Outcome Measures:

- Change From Baseline in Fasting Plasma Glucose (FPG) at Week 24 [Time Frame: Baseline and Week 24] [Designated as safety issue: No]

  Change from baseline at Week 24 is defined as FPG at Week 24 minus FPG at Week 0.

- Change From Baseline in 2-hour Post-meal Glucose (PMG) at Week 24 [Time Frame: Baseline and Week 24] [Designated as safety issue: No]

  Change from baseline at Week 24 is defined as PMG at Week 24 minus PMG at Week 0.

Enrollment:	701
Study Start Date:	June 2004
Study Completion Date:	February 2007
Primary Completion Date:	July 2005 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: Sitagliptin 100 mg The Sitagliptin 100 mg group includes patients who were administered once-daily treatment with oral tablets of sitagliptin 100 mg during Phase A (Weeks 0-24) of the treatment period. During Phase B (Weeks 24-104) of the treatment period these patients received once-daily coadministered treatment with oral tablets of sitagliptin 100 mg and glipizide-matched placebo.	Drug: Sitagliptin (MK0431) Sitagliptin 100 mg once daily, from Visit 4 through Final Visit, week 104 Other Names: • MK0431 • sitagliptin phosphate • Januvia Drug: Metformin Metformin 1500 mg, once daily, from Visit 2 to Final Visit (Week 104) Drug: Pioglitazone Pioglitazone 15 mg once daily, for patients not meeting specific glycemic goals during the placebo-controlled treatment period [Phase A], from Visit 5 (Week 6) to Visit 8 (Week 24) Other Name: ACTOS
Placebo Comparator: Placebo / Glipizide 5 mg The Placebo/Glipizide 5 mg group includes patients who were administered once-daily treatment with oral tablets of sitagliptin-matched placebo during Phase A (Weeks 0-24) of the treatment period. During Phase B (Weeks 24-104) of the treatment period these patients received once-daily coadministered treatment with oral tablets of sitagliptin-matched placebo 100 mg and glipizide 5 mg which was allowed to be uptitrated, in a blinded fashion, to a maximum dose of 15 mg/day.	Drug: Placebo/Glipizide 5 mg Placebo (to match Sitagliptin 100 mg) from Visit 4 through Visit 8; Glipizide 5 mg from Visit 8, week 24 to Final Visit (Week 104) Drug: Metformin Metformin 1500 mg, once daily, from Visit 2 to Final Visit (Week 104) Drug: Pioglitazone Pioglitazone 15 mg once daily, for patients not meeting specific glycemic goals during the placebo-controlled treatment period [Phase A], from Visit 5 (Week 6) to Visit 8 (Week 24) Other Name: ACTOS

Eligibility

Ages Eligible for Study:	18 Years to 78 Years
Genders Eligible for Study:	Both
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- Patients with type 2 diabetes mellitus

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: NCT00086515

Sponsors and Collaborators

Merck Sharp & Dohme Corp.

Investigators

Study Director: Medical Monitor Merck Sharp & Dohme Corp.

More Information

Publications:

Charbonnel B, Karasik A, Liu J, Wu M, Meininger G; Sitagliptin Study 020 Group. Efficacy and safety of the dipeptidyl peptidase-4 inhibitor sitagliptin added to ongoing metformin therapy in patients with type 2 diabetes inadequately controlled with metformin alone. Diabetes Care. 2006 Dec;29(12):2638-43.

Xu L, Man CD, Charbonnel B, Meninger G, Davies MJ, Williams-Herman D, Cobelli C, Stein PP. Effect of sitagliptin, a dipeptidyl peptidase-4 inhibitor, on beta-cell function in patients with type 2 diabetes: a model-based approach. Diabetes Obes Metab. 2008 Dec;10(12):1212-20. doi: 10.1111/j.1463-1326.2008.00887.x. Epub 2008 May 12.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00086515 History of Changes
Other Study ID Numbers:	0431-020 Formally-B0604T2DMT 2006_411
Study First Received:	July 2, 2004
Results First Received:	November 19, 2010
Last Updated:	April 27, 2015
Health Authority:	United States: Food and Drug Administration

Keywords provided by Merck Sharp & Dohme Corp.:
Type 2 Diabetes Mellitus

Additional relevant MeSH terms:

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

Sitagliptin
Dipeptidyl-Peptidase IV Inhibitors

Protease Inhibitors

ClinicalTrials.gov processed this record on April 13, 2016

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History of Changes

Results First Received: November 19, 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 II
Interventions:	Drug: Sitagliptin (MK0431) Drug: Placebo/Glipizide 5 mg Drug: Metformin Drug: 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

Primary therapy Period: 13-Jul-2004 through 02-Feb-2007 (for the 2-year Phase A and B periods); 100 study centers worldwide. (46 sites in the United States, 25 sites in 11 countries in Europe, and 29 sites in 13 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 18-78 years of age with type 2 diabetes mellitus with inadequate glycemic control (hemoglobin A1C [A1C] ≥7% and ≤10%) on stable doses of metformin (≥1500 mg/day) were eligible to enter the 104-week study.

Reporting Groups

	Description
Sitagliptin 100 mg	The Sitagliptin 100 mg group includes patients who were administered once-daily treatment with oral tablets of sitagliptin 100 mg during Phase A (Weeks 0-24) of the treatment period. During Phase B (Weeks 24-104) of the treatment period these patients received once-daily coadministered treatment with oral tablets of sitagliptin 100 mg and glipizide-matched placebo.
Placebo / Glipizide 5 mg	The Placebo/Glipizide 5 mg group includes patients who were administered once-daily treatment with oral tablets of sitagliptin-matched placebo during Phase A (Weeks 0-24) of the treatment period. During Phase B (Weeks 24-104) of the treatment period these patients received once-daily coadministered treatment with oral tablets of sitagliptin-matched placebo 100 mg and glipizide 5 mg which was allowed to be uptitrated, in a blinded fashion, to a maximum dose of 15 mg/day.

Participant Flow for 3 periods

Period 1: Phase A (Weeks 0-24)

	Sitagliptin 100 mg	Placebo / Glipizide 5 mg
STARTED	464	237
COMPLETED	415	192
NOT COMPLETED	49	45
Adverse Event	17	9
Lack of Efficacy	7	13
Lost to Follow-up	4	5
Protocol Violation	3	1
Withdrawal by Subject	10	10
Patient Moved	2	3
Protocol-Spec lab discon criteria	4	3
Poor compliance	1	0
Patient needed prohibited treatment	0	1
Personal Circumstance	1	0

Period 2: Phase A to Phase B Transition Period

	Sitagliptin 100 mg	Placebo / Glipizide 5 mg
STARTED	415	192
COMPLETED	391	164
NOT COMPLETED	24	28
Adverse Event	2	1
Lack of Efficacy	2	2
Withdrawal by Subject	1	0
Protocol Violation	0	1
Patient received Phase A rescue therapy		

	16	23
Protocol-Spec lab discon criteria	1	1
Poor compliance	1	0
Patient needed prohibited treatment	1	0

Period 3: Phase B (Weeks 24-104)

	Sitagliptin 100 mg	Placebo / Glipizide 5 mg
STARTED	391	164
COMPLETED	201	109
NOT COMPLETED	190	55
Adverse Event	16	10
Lack of Efficacy	94	19
Lost to Follow-up	13	4
Physician Decision	3	0
Protocol Violation	1	0
Withdrawal by Subject	15	5
Patient Moved	2	2
Protocol-Specific discontinuation	5	3
Protocol-Specific lab discon criteria	36	10
Patient Died	3	1
Patient needed prohibited treatment	0	1
Personal Circumstance	1	0
Discontinued in error	1	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 group includes patients who were administered once-daily treatment with oral tablets of sitagliptin 100 mg during Phase A (Weeks 0-24) of the treatment period. During Phase B (Weeks 24-104) of the treatment period these patients received once-daily coadministered treatment with oral tablets of sitagliptin 100 mg and glipizide-matched placebo.
Placebo / Glipizide 5 mg	The Placebo/Glipizide 5 mg group includes patients who were administered once-daily treatment with oral

	tablets of sitagliptin-matched placebo during Phase A (Weeks 0-24) of the treatment period. During Phase B (Weeks 24-104) of the treatment period these patients received once-daily coadministered treatment with oral tablets of sitagliptin-matched placebo 100 mg and glipizide 5 mg which was allowed to be uptitrated, in a blinded fashion, to a maximum dose of 15 mg/day.
Total	Total of all reporting groups

Baseline Measures

	Sitagliptin 100 mg	Placebo / Glipizide 5 mg	Total
Number of Participants [units: participants]	464	237	701
Age [units: years] Mean (Standard Deviation)	54.4 (10.4)	54.7 (9.7)	54.5 (10.2)
Gender [units: participants]			
Female	205	96	301
Male	259	141	400
Race/Ethnicity, Customized [units: participants]			
White	293	159	452
Black	31	14	45
Hispanic	72	28	100
Asian	49	26	75
Other	19	10	29
Fasting Plasma Glucose (FPG) [units: mg/dL] Mean (Standard Deviation)	170.2 (40.2)	174.1 (42.0)	171.5 (41.3)
Hemoglobin A1C (A1C) [units: Percent] Mean (Standard Deviation)	8.0 (0.8)	8.0 (0.8)	8.0 (0.8)

Outcome Measures

Hide All Outcome Measures

1. Primary: Change From Baseline in Hemoglobin A1C (A1C) at Week 24 [Time Frame: Baseline and Week 24]

Measure Type	Primary
Measure Title	Change From Baseline in Hemoglobin A1C (A1C) at Week 24
Measure Description	A1C is measured as a percent. Thus, this change from baseline reflects the Week 24 A1C percent minus the Week 0 A1C percent.
Time Frame	Baseline and Week 24
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The Full Analysis Set (FAS) included all patients with a baseline value and ≥1 post-baseline value for this outcome. Data following glycemic rescue were treated as missing. For FAS patients with no data at Week 24, the last non-baseline observed measurement was carried forward to Week 24.

Reporting Groups

	Description
Sitagliptin 100 mg	The Sitagliptin 100 mg group includes patients who were administered once-daily treatment with oral tablets of sitagliptin 100 mg during Phase A (Weeks 0-24) of the treatment period. During Phase B (Weeks 24-104) of the treatment period these patients received once-daily coadministered treatment with oral tablets of sitagliptin 100 mg and glipizide-matched placebo.
Placebo / Glipizide 5 mg	The Placebo/Glipizide 5 mg group includes patients who were administered once-daily treatment with oral tablets of sitagliptin-matched placebo during Phase A (Weeks 0-24) of the treatment period. During Phase B (Weeks 24-104) of the treatment period these patients received once-daily coadministered treatment with oral tablets of sitagliptin-matched placebo 100 mg and glipizide 5 mg which was allowed to be uptitrated, in a blinded fashion, to a maximum dose of 15 mg/day.

Measured Values

	Sitagliptin 100 mg	**Placebo / Glipizide 5 mg**
Number of Participants Analyzed [units: participants]	**453**	**224**
Change From Baseline in Hemoglobin A1C (A1C) at Week 24 [units: Percent] Least Squares Mean (95% Confidence Interval)	**-0.67 (-0.77 to -0.57)**	**-0.02 (-0.15 to 0.10)**

Statistical Analysis 1 for Change From Baseline in Hemoglobin A1C (A1C) at Week 24

Groups [1]	All groups
Method [2]	ANCOVA
P Value [3]	<0.001
Mean Difference (Final Values) [4]	-0.65
95% Confidence Interval	-0.77 to -0.53

[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, prior AHA status (not on AHA, on monotherapy oral AHA, or on metformin-based oral combination AHA), and baseline A1C
[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 Fasting Plasma Glucose (FPG) at Week 24 [Time Frame: Baseline and Week 24]

Measure Type	Secondary
Measure Title	Change From Baseline in Fasting Plasma Glucose (FPG) at Week 24
Measure Description	Change from baseline at Week 24 is defined as FPG at Week 24 minus FPG at Week 0.
Time Frame	Baseline and Week 24
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The Full Analysis Set (FAS) included all patients with a baseline value and ≥1 post-baseline value for this outcome. Data following glycemic rescue were treated as missing. For FAS patients with no data at Week 24, the last non-baseline observed measurement was carried forward to Week 24.

Reporting Groups

	Description
Sitagliptin 100 mg	The Sitagliptin 100 mg group includes patients who were administered once-daily treatment with oral tablets of sitagliptin 100 mg during Phase A (Weeks 0-24) of the treatment period. During Phase B (Weeks 24-104) of the treatment period these patients received once-daily coadministered treatment with oral tablets of sitagliptin 100 mg and glipizide-matched placebo.
Placebo / Glipizide 5 mg	The Placebo/Glipizide 5 mg group includes patients who were administered once-daily treatment with oral tablets of sitagliptin-matched placebo during Phase A (Weeks 0-24) of the treatment period. During Phase B (Weeks 24-104) of the treatment period these patients received once-daily coadministered treatment with oral tablets of sitagliptin-matched placebo 100 mg and glipizide 5 mg which was allowed to be uptitrated, in a blinded fashion, to a maximum dose of 15 mg/day.

Measured Values

	Sitagliptin 100 mg	**Placebo / Glipizide 5 mg**
Number of Participants Analyzed [units: participants]	**454**	**226**
Change From Baseline in Fasting Plasma Glucose (FPG) at Week 24 [units: mg/dL] Least Squares Mean (95% Confidence Interval)	**-16.9 (-21.5 to -12.3)**	**8.5 (2.9 to 14.1)**

Statistical Analysis 1 for Change From Baseline in Fasting Plasma Glucose (FPG) at Week 24

Groups [1]	All groups
[2]	

Method	ANCOVA
P Value [3]	<0.001
Mean Difference (Final Values) [4]	-25.4
95% Confidence Interval	-31.0 to -19.8

[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:
	Model terms: treatment, prior AHA status (not on AHA, on monotherapy oral AHA, or on metformin-based oral combination AHA), and baseline FPG
[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 2-hour Post-meal Glucose (PMG) at Week 24 [Time Frame: Baseline and Week 24]

Measure Type	Secondary
Measure Title	Change From Baseline in 2-hour Post-meal Glucose (PMG) at Week 24
Measure Description	Change from baseline at Week 24 is defined as PMG at Week 24 minus PMG at Week 0.
Time Frame	Baseline and Week 24
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The Full Analysis Set (FAS) included all patients with a baseline value and ≥1 post-baseline value for this outcome. Data following glycemic rescue were treated as missing. For FAS patients with no data at Week 24, the last non-baseline observed measurement was carried forward to Week 24.

Reporting Groups

	Description
Sitagliptin 100 mg	The Sitagliptin 100 mg group includes patients who were administered once-daily treatment with oral tablets of sitagliptin 100 mg during Phase A (Weeks 0-24) of the treatment period. During Phase B (Weeks 24-104) of the treatment period these patients received once-daily coadministered treatment with oral tablets of sitagliptin 100 mg and glipizide-matched placebo.
Placebo / Glipizide 5 mg	The Placebo/Glipizide 5 mg group includes patients who were administered once-daily treatment with oral tablets of sitagliptin-matched placebo during Phase A (Weeks 0-24) of the treatment period. During Phase B (Weeks 24-104) of the treatment period these patients received once-daily coadministered treatment with oral tablets of sitagliptin-matched placebo 100 mg and glipizide 5 mg which was allowed to be uptitrated, in a blinded fashion, to a maximum dose of 15 mg/day.

Measured Values

	Sitagliptin 100 mg	Placebo / Glipizide 5 mg
Number of Participants Analyzed [units: participants]	**387**	**182**
Change From Baseline in 2-hour Post-meal Glucose (PMG) at Week 24 [units: mg/dL] Least Squares Mean (95% Confidence Interval)	**-62.0 (-70.2 to -53.8)**	**-11.4 (-21.7 to -1.0)**

Statistical Analysis 1 for Change From Baseline in 2-hour Post-meal Glucose (PMG) at Week 24

Groups [1]	All groups
Method [2]	ANCOVA
P Value [3]	<0.001
Mean Difference (Final Values) [4]	-50.6
95% Confidence Interval	-60.5 to -40.8

[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:
	Model terms: treatment, prior AHA status (not on AHA, on monotherapy oral AHA, or on metformin-based oral combination AHA), and baseline 2-hour PMG
[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	Weeks 0-104
Additional Description	Patients received rescue medication if they met specific glycemic goals. Serious Adverse Events (SAEs) include events that occurred either before or after receiving rescue medication. Other Adverse Events (AEs) only includes those AEs that occurred prior to a patient receiving rescue medication.

Reporting Groups

	Description
Sitagliptin 100 mg	The Sitagliptin 100 mg group includes patients who were administered once-daily treatment with oral tablets of sitagliptin 100 mg during Phase A (Weeks 0-24) of the treatment period. During Phase B (Weeks 24-104) of the treatment period these patients received once-daily coadministered treatment with oral tablets of sitagliptin 100 mg

	and glipizide-matched placebo.
Placebo / Glipizide 5 mg	The Placebo/Glipizide 5 mg group includes patients who were administered once-daily treatment with oral tablets of sitagliptin-matched placebo during Phase A (Weeks 0-24) of the treatment period. During Phase B (Weeks 24-104) of the treatment period these patients received once-daily coadministered treatment with oral tablets of sitagliptin-matched placebo 100 mg and glipizide 5 mg which was allowed to be uptitrated, in a blinded fashion, to a maximum dose of 15 mg/day.

Serious Adverse Events

	Sitagliptin 100 mg	Placebo / Glipizide 5 mg
Total, serious adverse events		
# participants affected / at risk	**54/464 (11.64%)**	**21/237 (8.86%)**
Cardiac disorders		
Acute Myocardial Infarction [*1]		
# participants affected / at risk	**1/464 (0.22%)**	**1/237 (0.42%)**
Angina Pectoris [*1]		
# participants affected / at risk	**1/464 (0.22%)**	**0/237 (0.00%)**
Angina Unstable [*1]		
# participants affected / at risk	**1/464 (0.22%)**	**0/237 (0.00%)**
Atrial Fibrillation [*1]		
# participants affected / at risk	**0/464 (0.00%)**	**1/237 (0.42%)**
Cardiac Failure [*1]		
# participants affected / at risk	**1/464 (0.22%)**	**0/237 (0.00%)**
Coronary Artery Disease [*1]		
# participants affected / at risk	**1/464 (0.22%)**	**1/237 (0.42%)**
Myocardial Infarction [*1]		
# participants affected / at risk	**0/464 (0.00%)**	**1/237 (0.42%)**
Myocardial Ischaemia [*1]		
# participants affected / at risk	**0/464 (0.00%)**	**1/237 (0.42%)**
Tachyarrhythmia [*1]		
# participants affected / at risk	**1/464 (0.22%)**	**0/237 (0.00%)**
Eye disorders		
Cataract [*1]		
# participants affected / at risk	**1/464 (0.22%)**	**0/237 (0.00%)**
Papilloedema [*1]		
# participants affected / at risk	**1/464 (0.22%)**	**0/237 (0.00%)**
Gastrointestinal disorders		
Abdominal Pain [*1]		
# participants affected / at risk	**2/464 (0.43%)**	**0/237 (0.00%)**
Abdominal Strangulated Hernia [*1]		
# participants affected / at risk	**1/464 (0.22%)**	**0/237 (0.00%)**
Duodenal Ulcer Haemorrhage [*1]		

# participants affected / at risk	1/464 (0.22%)	0/237 (0.00%)
Inguinal Hernia * 1		
# participants affected / at risk	1/464 (0.22%)	0/237 (0.00%)
Melaena * 1		
# participants affected / at risk	1/464 (0.22%)	0/237 (0.00%)
Reflux Oesophagitis * 1		
# participants affected / at risk	1/464 (0.22%)	0/237 (0.00%)
Small Intestinal Obstruction * 1		
# participants affected / at risk	1/464 (0.22%)	0/237 (0.00%)
Upper Gastrointestinal Haemorrhage * 1		
# participants affected / at risk	1/464 (0.22%)	0/237 (0.00%)
General disorders		
Chest Pain * 1		
# participants affected / at risk	1/464 (0.22%)	0/237 (0.00%)
Death * 1		
# participants affected / at risk	2/464 (0.43%)	0/237 (0.00%)
Hernia * 1		
# participants affected / at risk	1/464 (0.22%)	0/237 (0.00%)
Non-Cardiac Chest Pain * 1		
# participants affected / at risk	1/464 (0.22%)	3/237 (1.27%)
Hepatobiliary disorders		
Biliary Colic * 1		
# participants affected / at risk	1/464 (0.22%)	0/237 (0.00%)
Cholangitis * 1		
# participants affected / at risk	1/464 (0.22%)	0/237 (0.00%)
Cholecystitis * 1		
# participants affected / at risk	1/464 (0.22%)	0/237 (0.00%)
Cholelithiasis * 1		
# participants affected / at risk	1/464 (0.22%)	0/237 (0.00%)
Hepatic Failure * 1		
# participants affected / at risk	0/464 (0.00%)	1/237 (0.42%)
Infections and infestations		
Abdominal Wall Infection * 1		
# participants affected / at risk	1/464 (0.22%)	0/237 (0.00%)
Bronchitis Acute * 1		
# participants affected / at risk	1/464 (0.22%)	0/237 (0.00%)
Cellulitis * 1		
# participants affected / at risk	1/464 (0.22%)	0/237 (0.00%)
Gastroenteritis * 1		
# participants affected / at risk	2/464 (0.43%)	0/237 (0.00%)
Helicobacter Gastritis * 1		

# participants affected / at risk	0/464 (0.00%)	1/237 (0.42%)
Infected Epidermal Cyst [*1]		
# participants affected / at risk	1/464 (0.22%)	0/237 (0.00%)
Liver Abscess [*1]		
# participants affected / at risk	0/464 (0.00%)	1/237 (0.42%)
Lobar Pneumonia [*1]		
# participants affected / at risk	1/464 (0.22%)	0/237 (0.00%)
Meningitis Bacterial [*1]		
# participants affected / at risk	1/464 (0.22%)	0/237 (0.00%)
Perirectal Abscess [*1]		
# participants affected / at risk	1/464 (0.22%)	0/237 (0.00%)
Pneumonia [*1]		
# participants affected / at risk	1/464 (0.22%)	0/237 (0.00%)
Pneumonia Primary Atypical [*1]		
# participants affected / at risk	0/464 (0.00%)	1/237 (0.42%)
Postoperative Wound Infection [*1]		
# participants affected / at risk	1/464 (0.22%)	0/237 (0.00%)
Pyelonephritis [*1]		
# participants affected / at risk	1/464 (0.22%)	0/237 (0.00%)
Upper Respiratory Tract Infection [*1]		
# participants affected / at risk	1/464 (0.22%)	0/237 (0.00%)
Urinary Tract Infection [*1]		
# participants affected / at risk	1/464 (0.22%)	0/237 (0.00%)
Injury, poisoning and procedural complications		
Gun Shot Wound [*1]		
# participants affected / at risk	0/464 (0.00%)	1/237 (0.42%)
Head Injury [*1]		
# participants affected / at risk	0/464 (0.00%)	1/237 (0.42%)
Joint Injury [*1]		
# participants affected / at risk	1/464 (0.22%)	0/237 (0.00%)
Polytraumatism [*1]		
# participants affected / at risk	2/464 (0.43%)	0/237 (0.00%)
Post Procedural Haemorrhage [*1]		
# participants affected / at risk	1/464 (0.22%)	0/237 (0.00%)
Tendon Rupture [*1]		
# participants affected / at risk	1/464 (0.22%)	1/237 (0.42%)
Traumatic Fracture [*1]		
# participants affected / at risk	0/464 (0.00%)	1/237 (0.42%)
Investigations		
Blood Creatine Phosphokinase Increased [*1]		
# participants affected / at risk	1/464 (0.22%)	0/237 (0.00%)

Blood Glucose Increased [*1]		
# participants affected / at risk	**1/464 (0.22%)**	**0/237 (0.00%)**
Metabolism and nutrition disorders		
Hyperglycaemia [*1]		
# participants affected / at risk	**1/464 (0.22%)**	**1/237 (0.42%)**
Musculoskeletal and connective tissue disorders		
Osteoarthritis [*1]		
# participants affected / at risk	**2/464 (0.43%)**	**0/237 (0.00%)**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
B-Cell Lymphoma [*1]		
# participants affected / at risk	**1/464 (0.22%)**	**0/237 (0.00%)**
Basal Cell Carcinoma [*1]		
# participants affected / at risk	**1/464 (0.22%)**	**0/237 (0.00%)**
Bladder Cancer [*1]		
# participants affected / at risk	**1/464 (0.22%)**	**0/237 (0.00%)**
Breast Cancer [*1]		
# participants affected / at risk	**1/464 (0.22%)**	**0/237 (0.00%)**
Clear Cell Carcinoma Of The Kidney [*1]		
# participants affected / at risk	**1/464 (0.22%)**	**0/237 (0.00%)**
Follicular Thyroid Cancer [*1]		
# participants affected / at risk	**1/464 (0.22%)**	**0/237 (0.00%)**
Hepatic Neoplasm Malignant [*1]		
# participants affected / at risk	**1/464 (0.22%)**	**0/237 (0.00%)**
Lung Neoplasm Malignant [*1]		
# participants affected / at risk	**0/464 (0.00%)**	**1/237 (0.42%)**
Ovarian Adenoma [*1]		
# participants affected / at risk	**1/464 (0.22%)**	**0/237 (0.00%)**
Pancreatic Carcinoma [*1]		
# participants affected / at risk	**1/464 (0.22%)**	**0/237 (0.00%)**
Papillary Thyroid Cancer [*1]		
# participants affected / at risk	**1/464 (0.22%)**	**0/237 (0.00%)**
Squamous Cell Carcinoma Of Skin [*1]		
# participants affected / at risk	**1/464 (0.22%)**	**0/237 (0.00%)**
Nervous system disorders		
Carotid Artery Stenosis [*1]		
# participants affected / at risk	**1/464 (0.22%)**	**0/237 (0.00%)**
Cerebrovascular Accident [*1]		
# participants affected / at risk	**1/464 (0.22%)**	**0/237 (0.00%)**
Ischaemic Stroke [*1]		
# participants affected / at risk	**1/464 (0.22%)**	**0/237 (0.00%)**

Loss Of Consciousness [*1]		
# participants affected / at risk	**0/464 (0.00%)**	**1/237 (0.42%)**
Subarachnoid Haemorrhage [*1]		
# participants affected / at risk	**1/464 (0.22%)**	**0/237 (0.00%)**
Syncope [*1]		
# participants affected / at risk	**1/464 (0.22%)**	**0/237 (0.00%)**
Transient Ischaemic Attack [*1]		
# participants affected / at risk	**0/464 (0.00%)**	**1/237 (0.42%)**
Psychiatric disorders		
Depression [*1]		
# participants affected / at risk	**1/464 (0.22%)**	**0/237 (0.00%)**
Renal and urinary disorders		
Calculus Ureteric [*1]		
# participants affected / at risk	**1/464 (0.22%)**	**0/237 (0.00%)**
Nephrolithiasis [*1]		
# participants affected / at risk	**0/464 (0.00%)**	**1/237 (0.42%)**
Nocturia [*1]		
# participants affected / at risk	**1/464 (0.22%)**	**0/237 (0.00%)**
Renal Colic [*1]		
# participants affected / at risk	**1/464 (0.22%)**	**0/237 (0.00%)**
Renal Failure [*1]		
# participants affected / at risk	**0/464 (0.00%)**	**1/237 (0.42%)**
Reproductive system and breast disorders		
Pelvic Haematoma [*1]		
# participants affected / at risk	**1/464 (0.22%)**	**0/237 (0.00%)**
Respiratory, thoracic and mediastinal disorders		
Acute Respiratory Failure [*1]		
# participants affected / at risk	**1/464 (0.22%)**	**0/237 (0.00%)**
Pulmonary Embolism [*1]		
# participants affected / at risk	**1/464 (0.22%)**	**0/237 (0.00%)**
Tracheal Stenosis [*1]		
# participants affected / at risk	**1/464 (0.22%)**	**0/237 (0.00%)**
Skin and subcutaneous tissue disorders		
Urticaria [*1]		
# participants affected / at risk	**0/464 (0.00%)**	**1/237 (0.42%)**
Surgical and medical procedures		
Finger Amputation [*1]		
# participants affected / at risk	**1/464 (0.22%)**	**0/237 (0.00%)**
Vascular disorders		
Arteriosclerosis [*1]		
# participants affected / at risk	**1/464 (0.22%)**	**0/237 (0.00%)**

Hypertension * 1		
# participants affected / at risk	**1/464 (0.22%)**	**0/237 (0.00%)**
Leriche Syndrome * 1		
# participants affected / at risk	**1/464 (0.22%)**	**0/237 (0.00%)**

* Events were collected by non-systematic assessment
1 Term from vocabulary, MedDRA (9.1)

Other Adverse Events

Hide Other Adverse Events

Time Frame	Weeks 0-104
Additional Description	Patients received rescue medication if they met specific glycemic goals. Serious Adverse Events (SAEs) include events that occurred either before or after receiving rescue medication. Other Adverse Events (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 group includes patients who were administered once-daily treatment with oral tablets of sitagliptin 100 mg during Phase A (Weeks 0-24) of the treatment period. During Phase B (Weeks 24-104) of the treatment period these patients received once-daily coadministered treatment with oral tablets of sitagliptin 100 mg and glipizide-matched placebo.
Placebo / Glipizide 5 mg	The Placebo/Glipizide 5 mg group includes patients who were administered once-daily treatment with oral tablets of sitagliptin-matched placebo during Phase A (Weeks 0-24) of the treatment period. During Phase B (Weeks 24-104) of the treatment period these patients received once-daily coadministered treatment with oral tablets of sitagliptin-matched placebo 100 mg and glipizide 5 mg which was allowed to be uptitrated, in a blinded fashion, to a maximum dose of 15 mg/day.

Other Adverse Events

	Sitagliptin 100 mg	**Placebo / Glipizide 5 mg**
Total, other (not including serious) adverse events		
# participants affected / at risk	**210/464 (45.26%)**	**124/237 (52.32%)**
Gastrointestinal disorders		
Diarrhoea * 1		
# participants affected / at risk	**28/464 (6.03%)**	**11/237 (4.64%)**
Infections and infestations		
Bronchitis * 1		
# participants affected / at risk	**26/464 (5.60%)**	**12/237 (5.06%)**
Influenza * 1		

# participants affected / at risk	37/464 (7.97%)	20/237 (8.44%)
Nasopharyngitis * 1		
# participants affected / at risk	41/464 (8.84%)	16/237 (6.75%)
Upper Respiratory Tract Infection * 1		
# participants affected / at risk	49/464 (10.56%)	29/237 (12.24%)
Urinary Tract Infection * 1		
# participants affected / at risk	22/464 (4.74%)	13/237 (5.49%)
Investigations		
Blood Glucose Increased * 1		
# participants affected / at risk	8/464 (1.72%)	14/237 (5.91%)
Metabolism and nutrition disorders		
Hypoglycaemia * 1		
# participants affected / at risk	17/464 (3.66%)	41/237 (17.30%)
Musculoskeletal and connective tissue disorders		
Back Pain * 1		
# participants affected / at risk	33/464 (7.11%)	20/237 (8.44%)
Nervous system disorders		
Headache * 1		
# participants affected / at risk	20/464 (4.31%)	13/237 (5.49%)
Vascular disorders		
Hypertension * 1		
# participants affected / at risk	29/464 (6.25%)	18/237 (7.59%)

* Events were collected by non-systematic assessment
1 Term from vocabulary, MedDRA (9.1)

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:

Charbonnel B, Karasik A, Liu J, Wu M, Meininger G; Sitagliptin Study 020 Group. Efficacy and safety of the dipeptidyl peptidase-4 inhibitor sitagliptin added to ongoing metformin therapy in patients with type 2 diabetes inadequately controlled with metformin alone. Diabetes Care. 2006 Dec;29(12):2638-43.

Xu L, Man CD, Charbonnel B, Meninger G, Davies MJ, Williams-Herman D, Cobelli C, Stein PP. Effect of sitagliptin, a dipeptidyl peptidase-4 inhibitor, on beta-cell function in patients with type 2 diabetes: a model-based approach. Diabetes Obes Metab. 2008 Dec;10(12):1212-20. doi: 10.1111/j.1463-1326.2008.00887.x. Epub 2008 May 12.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00086515 History of Changes
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Study First Received:	July 2, 2004
Results First Received:	November 19, 2010
Last Updated:	April 27, 2015
Health Authority:	United States: Food and Drug Administration

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