Sitagliptin Comparative Study in Patients With Type 2 Diabetes (0431-049)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

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

ClinicalTrials.gov Identifier:
NCT00449930

First received: March 19, 2007
Last updated: April 27, 2015
Last verified: April 2015
History of Changes

Purpose

A study to evaluate the efficacy and safety of sitagliptin in comparison to a commonly used medication in patients with type 2 diabetes

Condition	Intervention	Phase
Type 2 Diabetes Mellitus	Drug: sitagliptin phosphate Drug: Comparator: metformin hydrochloride	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, Double-Blind, Randomized Study to Evaluate the Safety and Efficacy of Sitagliptin Compared With Metformin in Patients With Type 2 Diabetes Mellitus With Inadequate Glycemic Control

Resource links provided by NLM:

MedlinePlus related topics: Diabetes Type 2

Drug Information available for: Metformin Metformin 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 (HbA1c) at Week 24 [Time Frame: Baseline and 24 weeks] [Designated as safety issue: No]

HbA1c is measured as a percent. Thus, this change from baseline reflects the Week 24 HbA1c percent minus the Week 0 HbA1c percent.

Secondary Outcome Measures:

- Number of Patients Who Reported 1 or More Episodes of the Adverse Experience of Diarrhea [Time Frame: Baseline to Week 24] [Designated as safety issue: No]
- Number of Patients Who Reported 1 or More Episodes of the Adverse Experience of Nausea [Time Frame: Baseline to Week 24] [Designated as safety issue: No]
- Number of Patients Who Reported 1 or More Episodes of the Adverse Experience of Abdominal Pain [Time Frame: Baseline to Week 24] [Designated as safety issue: No]
- Number of Patients Who Reported 1 or More Episodes of the Adverse Experience of Vomiting [Time Frame: Baseline to Week 24] [Designated as safety issue: No]

Enrollment:	1050
Study Start Date:	March 2007
Study Completion Date:	July 2008
Primary Completion Date:	July 2008 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: 1 Drug	Drug: sitagliptin phosphate (1) sitagliptin 100mg tablet once daily (q.d.) for a 24-wk treatment period Other Name: MK0431
Active Comparator: 2 Active comparator	Drug: Comparator: metformin hydrochloride (4) Metformin 500mg tablets once daily (q.d.) for a 24-wk treatment period.

Eligibility

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

Criteria

General Inclusion Criteria:

- Patient has type 2 diabetes mellitus (T2DM)
- Patient is inadequately controlled and not on treatment with insulin or oral antihyperglycemic therapy

General Exclusion Criteria:

- Patient has a history of type 1 diabetes mellitus or history of ketoacidosis
- Patient was on antihyperglycemic therapy (insulin or oral) within the prior 4 months

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: NCT00449930

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:

Aschner P, Katzeff HL, Guo H, Sunga S, Williams-Herman D, Kaufman KD, Goldstein BJ; Sitagliptin Study 049 Group. Efficacy and safety of monotherapy of sitagliptin compared with metformin in patients with type 2 diabetes. Diabetes Obes Metab. 2010 Mar;12(3):252-61. doi: 10.1111/j.1463-1326.2009.01187.x. Epub 2009 Nov 25.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00449930 History of Changes
Other Study ID Numbers:	0431-049 MK0431-049 2006_561
Study First Received:	March 19, 2007
Results First Received:	June 23, 2009
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
Metformin	Pharmacologic Actions
Sitagliptin	Physiological Effects of Drugs
Dipeptidyl-Peptidase IV Inhibitors	Protease Inhibitors
Enzyme Inhibitors	

ClinicalTrials.gov processed this record on April 13, 2016

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Results First Received: June 23, 2009

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:	Type 2 Diabetes Mellitus
Interventions:	Drug: sitagliptin phosphate Drug: Comparator: metformin hydrochloride

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: 04-Apr-2007

Last Patient Last Visit: 25-Jul-2008

113 study centers worldwide

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 (T2DM) who were not on anti-hyperglycemic agents for at least 4 months (16 weeks) and with a hemoglobin A1c (HbA1c) of ≥ 6.5 and ≤9.0%

Reporting Groups

	Description
Sitagliptin 100 mg	The Sitagliptin 100 mg group includes data from patients randomized to receive treatment with 100 mg oral tablet of sitagliptin once daily.
Metformin	The Metformin group includes data from patients randomized to receive treatment with metformin initiated at a dose of 1 tablet (500 mg) per day. Patients were then to be up-titrated over a maximum of 5 weeks to a total daily dose of 2 tablets twice daily (1000 mg b.i.d).

Participant Flow: Overall Study

	Sitagliptin 100 mg	Metformin
STARTED	**528**	**522**
COMPLETED	**467**	**447**
NOT COMPLETED	**61**	**75**
Adverse Event	**9**	**19**
Trial Terminated (Site Closed)	**1**	**0**
Lack of Efficacy	**10**	**1**
Lost to Follow-up	**9**	**14**
Physician Decision	**1**	**2**
Protocol Violation	**14**	**15**
Withdrawal by Subject	**16**	**23**
Glycemic discontinuation criteria	**1**	**1**

Baseline Characteristics

Hide Baseline Characteristics

Population Description

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

Reporting Groups

	Description
Sitagliptin 100 mg	The Sitagliptin 100 mg group includes data from patients randomized to receive treatment with 100 mg oral tablet of sitagliptin once daily.
Metformin	The Metformin group includes data from patients randomized to receive treatment with metformin initiated at a dose of 1 tablet (500 mg) per day. Patients were then to be up-titrated over a maximum of 5 weeks to a total daily dose of 2 tablets twice daily (1000 mg b.i.d).
Total	Total of all reporting groups

Baseline Measures

	Sitagliptin 100 mg	Metformin	Total

Number of Participants [units: participants]	**528**	**522**	**1050**
Age [units: years] Mean (Standard Deviation)	**55.9 (10.7)**	**56.1 (10.4)**	**56.0 (10.6)**
Gender [units: participants]			
Female	**278**	**288**	**566**
Male	**250**	**234**	**484**
Race/Ethnicity, Customized [units: participants]			
White	**397**	**395**	**792**
Black	**24**	**19**	**43**
Asian	**64**	**62**	**126**
Other	**43**	**46**	**89**
Body Weight [units: Kilograms] Mean (Standard Deviation)	**84.9 (17.7)**	**84.6 (17.2)**	**84.7 (17.5)**
Hemoglobin A1c (HbA1c) [units: Percent] Mean (Standard Deviation)	**7.2 (0.7)**	**7.3 (0.7)**	**7.3 (0.7)**

Outcome Measures

Hide All Outcome Measures

1. Primary: Change From Baseline in Hemoglobin A1c (HbA1c) at Week 24 [Time Frame: Baseline and 24 weeks]

Measure Type	Primary
Measure Title	Change From Baseline in Hemoglobin A1c (HbA1c) at Week 24
Measure Description	HbA1c is measured as a percent. Thus, this change from baseline reflects the Week 24 HbA1c percent minus the Week 0 HbA1c percent.
Time Frame	Baseline and 24 weeks
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 per protocol population required that a patient had measurements both at baseline and at Week 24, and did not have any major protocol violations (e.g. drug compliance <85%, addition of prohibited antihyperglycemic agent, incorrect double-blind study medication). No missing data were imputed.

Reporting Groups

	Description
Sitagliptin 100 mg	The Sitagliptin 100 mg group includes data from patients randomized to receive treatment with 100 mg oral tablet of

	sitagliptin once daily.
Metformin	The Metformin group includes data from patients randomized to receive treatment with metformin initiated at a dose of 1 tablet (500 mg) per day. Patients were then to be up-titrated over a maximum of 5 weeks to a total daily dose of 2 tablets twice daily (1000 mg b.i.d).

Measured Values

	Sitagliptin 100 mg	Metformin
Number of Participants Analyzed [units: participants]	**455**	**439**
Change From Baseline in Hemoglobin A1c (HbA1c) at Week 24 [units: Percent] Least Squares Mean (95% Confidence Interval)	**-0.43 (-0.48 to -0.38)**	**-0.57 (-0.62 to -0.51)**

Statistical Analysis 1 for Change From Baseline in Hemoglobin A1c (HbA1c) at Week 24

Groups [1]	All groups
Non-Inferiority/Equivalence Test [2]	Yes
Mean Difference (Net) [3]	0.14
Standard Deviation	(0.57)
95% Confidence Interval	0.06 to 0.21

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Details of power calculation, definition of non-inferiority margin, and other key parameters:
	The pre-specified non-inferiority margin was 0.4%; i.e., non-inferiority required that the upper boundary of the 95% confidence interval for the treatment difference (sitagliptin minus metformin) to be less than 0.4%.
[3]	Other relevant estimation information:
	Based on an analysis of covariance (ANCOVA) model with terms for treatment group and baseline value.

2. Secondary: Number of Patients Who Reported 1 or More Episodes of the Adverse Experience of Diarrhea [Time Frame: Baseline to Week 24]

Measure Type	Secondary
Measure Title	Number of Patients Who Reported 1 or More Episodes of the Adverse Experience of Diarrhea
Measure Description	No text entered.
Time Frame	Baseline to 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.
All randomized patients who received at least 1 dose of the double-blind study therapy.

Reporting Groups

	Description
Sitagliptin 100 mg	The Sitagliptin 100 mg group includes data from patients randomized to receive treatment with 100 mg oral tablet of sitagliptin once daily.
Metformin	The Metformin group includes data from patients randomized to receive treatment with metformin initiated at a dose of 1 tablet (500 mg) per day. Patients were then to be up-titrated over a maximum of 5 weeks to a total daily dose of 2 tablets twice daily (1000 mg b.i.d).

Measured Values

	Sitagliptin 100 mg	Metformin
Number of Participants Analyzed [units: participants]	**528**	**522**
Number of Patients Who Reported 1 or More Episodes of the Adverse Experience of Diarrhea [units: Participants]		
Patients Who Reported Diarrhea	**19**	**57**
Patients Who Did Not Report Diarrhea	**509**	**465**

Statistical Analysis 1 for Number of Patients Who Reported 1 or More Episodes of the Adverse Experience of Diarrhea

Groups [1]	All groups
Method [2]	Fisher Exact
P Value [3]	<0.001
Risk Difference (RD) [4]	-7.3
95% Confidence Interval	-10.6 to -4.2

[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:
	Difference (sitagliptin minus metformin) in the percentage of patients with diarrhea. Wilson Score method was used for the 95% Confidence Interval (CI).

3. Secondary: Number of Patients Who Reported 1 or More Episodes of the Adverse Experience of Nausea [Time Frame: Baseline to Week 24]

Measure Type	Secondary
Measure Title	

	Number of Patients Who Reported 1 or More Episodes of the Adverse Experience of Nausea
Measure Description	No text entered.
Time Frame	Baseline to 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.
All randomized patients who received at least 1 dose of the double-blind study therapy.

Reporting Groups

	Description
Sitagliptin 100 mg	The Sitagliptin 100 mg group includes data from patients randomized to receive treatment with 100 mg oral tablet of sitagliptin once daily.
Metformin	The Metformin group includes data from patients randomized to receive treatment with metformin initiated at a dose of 1 tablet (500 mg) per day. Patients were then to be up-titrated over a maximum of 5 weeks to a total daily dose of 2 tablets twice daily (1000 mg b.i.d).

Measured Values

	Sitagliptin 100 mg	**Metformin**
Number of Participants Analyzed [units: participants]	**528**	**522**
Number of Patients Who Reported 1 or More Episodes of the Adverse Experience of Nausea [units: Participants]		
Patients Who Reported Nausea	**6**	**16**
Patients Who Did Not Report Nausea	**522**	**506**

Statistical Analysis 1 for Number of Patients Who Reported 1 or More Episodes of the Adverse Experience of Nausea

Groups [1]	All groups
Method [2]	Fisher Exact
P Value [3]	0.032
Risk Difference (RD) [4]	-1.9
95% Confidence Interval	-3.9 to -0.2

[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:
	Difference (sitagliptin minus metformin) in the percentage of patients with nausea. Wilson Score method was used for the 95% CI.

4. Secondary: Number of Patients Who Reported 1 or More Episodes of the Adverse Experience of Abdominal Pain [Time Frame: Baseline to Week 24]

Measure Type	Secondary
Measure Title	Number of Patients Who Reported 1 or More Episodes of the Adverse Experience of Abdominal Pain
Measure Description	No text entered.
Time Frame	Baseline to 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.
All randomized patients who received at least 1 dose of the double-blind study therapy.

Reporting Groups

	Description
Sitagliptin 100 mg	The Sitagliptin 100 mg group includes data from patients randomized to receive treatment with 100 mg oral tablet of sitagliptin once daily.
Metformin	The Metformin group includes data from patients randomized to receive treatment with metformin initiated at a dose of 1 tablet (500 mg) per day. Patients were then to be up-titrated over a maximum of 5 weeks to a total daily dose of 2 tablets twice daily (1000 mg b.i.d).

Measured Values

	Sitagliptin 100 mg	**Metformin**
Number of Participants Analyzed [units: participants]	**528**	**522**
Number of Patients Who Reported 1 or More Episodes of the Adverse Experience of Abdominal Pain [units: Participants]		
Patients Who Reported Abdominal Pain	**11**	**20**
Patients Who Did Not Report Abdominal Pain	**517**	**502**

Statistical Analysis 1 for Number of Patients Who Reported 1 or More Episodes of the Adverse Experience of Abdominal Pain

Groups [1]	All groups
Method [2]	Fisher Exact
P Value [3]	0.103
Risk Difference (RD) [4]	-1.7

95% Confidence Interval	-4.0 to 0.3

[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:
	Difference (sitagliptin minus metformin) in the percentage of patients with abdominal pain. Wilson Score method was used for the 95% CI.

5. Secondary: Number of Patients Who Reported 1 or More Episodes of the Adverse Experience of Vomiting [Time Frame: Baseline to Week 24]

Measure Type	Secondary
Measure Title	Number of Patients Who Reported 1 or More Episodes of the Adverse Experience of Vomiting
Measure Description	No text entered.
Time Frame	Baseline to 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.
All randomized patients who received at least 1 dose of the double-blind study therapy.

Reporting Groups

	Description
Sitagliptin 100 mg	The Sitagliptin 100 mg group includes data from patients randomized to receive treatment with 100 mg oral tablet of sitagliptin once daily.
Metformin	The Metformin group includes data from patients randomized to receive treatment with metformin initiated at a dose of 1 tablet (500 mg) per day. Patients were then to be up-titrated over a maximum of 5 weeks to a total daily dose of 2 tablets twice daily (1000 mg b.i.d).

Measured Values

	Sitagliptin 100 mg	**Metformin**
Number of Participants Analyzed [units: participants]	**528**	**522**
Number of Patients Who Reported 1 or More Episodes of the Adverse Experience of Vomiting [units: Participants]		

Patients Who Reported Vomiting	**2**	**7**
Patients Who Did Not Report Vomiting	**526**	**515**

Statistical Analysis 1 for Number of Patients Who Reported 1 or More Episodes of the Adverse Experience of Vomiting

Groups [1]	All groups
Risk Difference (RD) [2]	-1.0
95% Confidence Interval	-2.4 to 0.2

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant estimation information:
	Difference (sitagliptin minus metformin) in the percentage of patients with vomiting. Wilson Score method was used for the 95% CI.

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	No text entered.
Additional Description	No text entered.

Reporting Groups

	Description
Sitagliptin 100 mg	The Sitagliptin 100 mg group includes data from patients randomized to receive treatment with 100 mg oral tablet of sitagliptin once daily.
Metformin	The Metformin group includes data from patients randomized to receive treatment with metformin initiated at a dose of 1 tablet (500 mg) per day. Patients were then to be up-titrated over a maximum of 5 weeks to a total daily dose of 2 tablets twice daily (1000 mg b.i.d).

Serious Adverse Events

	Sitagliptin 100 mg	**Metformin**
Total, serious adverse events		
# participants affected	**10**	**8**
Cardiac disorders		
Any Cardiac disorders * 1		
# participants affected / at risk	**1/528 (0.19%)**	**3/522 (0.57%)**
Acute myocardial infarction * 1		
# participants affected / at risk	**0/528 (0.00%)**	**1/522 (0.19%)**

Angina pectoris [*1]		
# participants affected / at risk	1/528 (0.19%)	0/522 (0.00%)
Coronary artery disease [*1]		
# participants affected / at risk	0/528 (0.00%)	1/522 (0.19%)
Tachyarrhythmia [*1]		
# participants affected / at risk	0/528 (0.00%)	1/522 (0.19%)
Congenital, familial and genetic disorders		
Any Congenital, familial and genetic disorders [*1]		
# participants affected / at risk	0/528 (0.00%)	1/522 (0.19%)
Multiple endocrine adenomatosis Type II [*1]		
# participants affected / at risk	0/528 (0.00%)	1/522 (0.19%)
General disorders		
Any General disorders and administration site conditions [*1]		
# participants affected / at risk	0/528 (0.00%)	1/522 (0.19%)
Non-cardiac chest pain [*1]		
# participants affected / at risk	0/528 (0.00%)	1/522 (0.19%)
Infections and infestations		
Any Infections and infestations [*1]		
# participants affected / at risk	2/528 (0.38%)	2/522 (0.38%)
Appendicitis [*1]		
# participants affected / at risk	1/528 (0.19%)	0/522 (0.00%)
Cellulitis [*1]		
# participants affected / at risk	0/528 (0.00%)	1/522 (0.19%)
Gastroenteritis [*1]		
# participants affected / at risk	1/528 (0.19%)	0/522 (0.00%)
Upper respiratory tract infection [*1]		
# participants affected / at risk	0/528 (0.00%)	1/522 (0.19%)
Injury, poisoning and procedural complications		
Any Injury, poisoning and procedural complications [*1]		
# participants affected / at risk	3/528 (0.57%)	0/522 (0.00%)
Intervertebral disc injury [*1]		
# participants affected / at risk	1/528 (0.19%)	0/522 (0.00%)

Joint injury [*1]		
# participants affected / at risk	1/528 (0.19%)	0/522 (0.00%)
Tibia fracture [*1]		
# participants affected / at risk	1/528 (0.19%)	0/522 (0.00%)
Metabolism and nutrition disorders		
Any Metabolism and nutrition disorders [*1]		
# participants affected / at risk	1/528 (0.19%)	0/522 (0.00%)
Hypoglycaemia [*1]		
# participants affected / at risk	1/528 (0.19%)	0/522 (0.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Any Neoplasms benign, malignant and unspecified [*1]		
# participants affected / at risk	1/528 (0.19%)	1/522 (0.19%)
Lung carcinoma cell type unspecified stage IV [*1]		
# participants affected / at risk	1/528 (0.19%)	0/522 (0.00%)
Malignant melanoma [*1]		
# participants affected / at risk	0/528 (0.00%)	1/522 (0.19%)
Metastases to bone [*1]		
# participants affected / at risk	1/528 (0.19%)	0/522 (0.00%)
Nervous system disorders		
Any Nervous system disorders [*1]		
# participants affected / at risk	1/528 (0.19%)	0/522 (0.00%)
Facial palsy [*1]		
# participants affected / at risk	1/528 (0.19%)	0/522 (0.00%)
Renal and urinary disorders		
Any Renal and urinary disorders [*1]		
# participants affected / at risk	1/528 (0.19%)	0/522 (0.00%)
Nephrolithiasis [*1]		
# participants affected / at risk	1/528 (0.19%)	0/522 (0.00%)
Reproductive system and breast disorders		
Any Reproductive system and breast disorders [*1]		
# participants affected / at risk	0/528 (0.00%)	1/522 (0.19%)
Hydrometra [*1]		

# participants affected / at risk	**0/528 (0.00%)**	**1/522 (0.19%)**

* Events were collected by non-systematic assessment
1 Term from vocabulary, MedDRA 11.0

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%

Reporting Groups

	Description
Sitagliptin 100 mg	The Sitagliptin 100 mg group includes data from patients randomized to receive treatment with 100 mg oral tablet of sitagliptin once daily.
Metformin	The Metformin group includes data from patients randomized to receive treatment with metformin initiated at a dose of 1 tablet (500 mg) per day. Patients were then to be up-titrated over a maximum of 5 weeks to a total daily dose of 2 tablets twice daily (1000 mg b.i.d).

Other Adverse Events

	Sitagliptin 100 mg	Metformin
Total, other (not including serious) adverse events		
# participants affected	**19**	**57**
Gastrointestinal disorders		
Any Gastrointestinal disorders [* 1]		
# participants affected / at risk	**19/528 (3.60%)**	**57/522 (10.92%)**
Diarrhoea [* 1]		
# participants affected / at risk	**19/528 (3.60%)**	**57/522 (10.92%)**

* Events were collected by non-systematic assessment
1 Term from vocabulary, MedDRA 11.0

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

Site 0490125 was non-compliant with Good Clinical Practice (GCP). Data from the 8 patients at this site were removed from all analyses.

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

Publications of Results:

Aschner P, Katzeff HL, Guo H, Sunga S, Williams-Herman D, Kaufman KD, Goldstein BJ; Sitagliptin Study 049 Group. Efficacy and safety of monotherapy of sitagliptin compared with metformin in patients with type 2 diabetes. Diabetes Obes Metab. 2010 Mar;12(3):252-61. doi: 10.1111/j.1463-1326.2009.01187.x. Epub 2009 Nov 25.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00449930 History of Changes
Other Study ID Numbers:	0431-049 MK0431-049 2006_561
Study First Received:	March 19, 2007
Results First Received:	June 23, 2009
Last Updated:	April 27, 2015
Health Authority:	United States: Food and Drug Administration

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