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Sitagliptin Metformin/PPARg Agonist Combination Therapy Add-on (0431-052)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

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

ClinicalTrials.gov Identifier:
NCT00350779

First received: July 7, 2006
Last updated: February 3, 2016
Last verified: February 2016
History of Changes

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Purpose

A clinical study to determine the safety and efficacy of sitagliptin in patients with Type 2 Diabetes Mellitus who have inadequate glycemic control on metformin/peroxisome proliferator-activated receptor gamma (PPARg) agonist combination therapy.

Condition	Intervention	Phase
Type 2 Diabetes Mellitus	Drug: sitagliptin Drug: Comparator: Placebo Drug: rosiglitazone Drug: metformin Drug: glipizide	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 Phase III Randomized, Placebo-Controlled Clinical Trial to Study the Safety and Efficacy of the Addition of Sitagliptin (MK0431) in Patients With Type 2 Diabetes Mellitus Who Have Inadequate Glycemic Control on Combination Therapy With Metformin and a PPARg Agonist

Resource links provided by NLM:

MedlinePlus related topics: Diabetes Type 2

Drug Information available for: Metformin Metformin hydrochloride Glipizide Rosiglitazone Rosiglitazone Maleate Sitagliptin Sitagliptin phosphate

U.S. FDA Resources

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

Primary Outcome Measures:

- Change From Baseline in HbA1c (Hemoglobin A1C) at Week 18 [Time Frame: Baseline and 18 Weeks] [Designated as safety issue: No]

  HbA1c is measured as a percent. Thus, this change from baseline reflects the Week 18 HbA1c percent minus the Week 0 HbA1c percent.

Secondary Outcome Measures:

- Change From Baseline in FPG (Fasting Plasma Glucose) at Week 18 [Time Frame: Baseline and 18 Weeks] [Designated as safety issue: No]

  Change from baseline at Week 18 is defined as Week 18 minus Week 0

- Change From Baseline in 2-hour PMG (Post-meal Glucose) at Week 18 [Time Frame: Baseline and Week 18] [Designated as safety issue: No]

  Change from baseline at Week 18 is defined as Week 18 minus Week 0

- Change From Baseline in HbA1c (Hemoglobin A1C) at Week 54 [Time Frame: Baseline and Week 54] [Designated as safety issue: No]

  HbA1c is measured as a percent. Thus, this change from baseline reflects the Week 54 HbA1c percent minus the Week 0 HbA1c percent.

- Change From Baseline in FPG (Fasting Plasma Glucose) at Week 54 [Time Frame: Baseline and Week 54] [Designated as safety issue: No]

  Change from baseline at Week 54 is defined as Week 54 minus Week 0

- Change From Baseline in 2-hour PMG (Post-meal Glucose) at Week 54 [Time Frame: Baseline and Week 54] [Designated as safety issue: No]

  Change from baseline at Week 54 is defined as Week 54 minus Week 0.

Enrollment:	262
Study Start Date:	June 2006
Study Completion Date:	June 2008
Primary Completion Date:	September 2007 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: 1 Sitagliptin	Drug: sitagliptin Sitagliptin 100mg tablet each day for 54 weeks. All subjects will be given placebo to sitagliptin for a 2 week period. Other Name: Januvia Drug: rosiglitazone Subjects taking 4mg or greater rosiglitazone at screening will enter a 6 week stable dose period followed by a 54 week treatment period. Subjects who are taking less than 4mg/day or no rosiglitazone at screening will be titrated to a stable dose of at least 4mg over a a maximum of 8 weeks followed by a dose stable period of up to 12 weeks then a 54 week treatment period. Total treatment will be up to 77 weeks. Other Name: Avandia Drug: metformin Subjects taking 1500mg or greater metformin at screening will enter a 6 week stable dose period followed by a 54 week treatment period. Subjects who are taking less than 1500mg/day or no metformin at screening will be titrated to a stable dose of at least 1500mg over a a maximum of 8 weeks followed by a dose stable period of up to 12 weeks then a 54 week treatment period. Total treatment will be up to 77 weeks. Drug: glipizide Subjects not meeting specific glycemic controls during the 54-week treatment period will use glipizide as rescue therapy. Glipizide will be titrated in 5mg doses up to a maximum 40mg each day. (In Canada, the rescue therapy will be a sulfonylurea agent marketed in that country.) Other Name: Glucotrol
Placebo Comparator:	Drug: Comparator: Placebo Placebo to sitagliptin 100mg tablet each day for 54 weeks.

2 Placebo	Drug: rosiglitazone Subjects taking 4mg or greater rosiglitazone at screening will enter a 6 week stable dose period followed by a 54 week treatment period. Subjects who are taking less than 4mg/day or no rosiglitazone at screening will be titrated to a stable dose of at least 4mg over a a maximum of 8 weeks followed by a dose stable period of up to 12 weeks then a 54 week treatment period. Total treatment will be up to 77 weeks. Other Name: Avandia Drug: metformin Subjects taking 1500mg or greater metformin at screening will enter a 6 week stable dose period followed by a 54 week treatment period. Subjects who are taking less than 1500mg/day or no metformin at screening will be titrated to a stable dose of at least 1500mg over a a maximum of 8 weeks followed by a dose stable period of up to 12 weeks then a 54 week treatment period. Total treatment will be up to 77 weeks. Drug: glipizide Subjects not meeting specific glycemic controls during the 54-week treatment period will use glipizide as rescue therapy. Glipizide will be titrated in 5mg doses up to a maximum 40mg each day. (In Canada, the rescue therapy will be a sulfonylurea agent marketed in that country.) Other Name: Glucotrol

Eligibility

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

Criteria

Inclusion Criteria:

- Patient has type 2 diabetes mellitus
- Patient is inadequately controlled while taking two oral antidiabetic medications

Exclusion Criteria:

- Patient has a history of type 1 diabetes mellitus or history of ketoacidosis
- Patient required insulin therapy within the prior 3 months
- Patient has been taking Byetta (R) (exenatide) within the prior 3 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: NCT00350779

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 automatically indexed to this study by ClinicalTrials.gov Identifier (NCT Number):

Dobs AS, Goldstein BJ, Aschner P, Horton ES, Umpierrez GE, Duran L, Hill JS, Chen Y, Golm GT, Langdon RB, Williams-Herman DE, Kaufman KD, Amatruda JM, Ferreira JC. Efficacy and safety of sitagliptin added to ongoing metformin and rosiglitazone combination therapy in a randomized placebo-controlled 54-week trial in patients with type 2 diabetes. J Diabetes. 2013 Mar;5(1):68-79. doi: 10.1111/j.1753-0407.2012.00223.x.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00350779 History of Changes
Other Study ID Numbers:	0431-052 MK0431-052 2006_507
Study First Received:	July 7, 2006
Results First Received:	May 13, 2009
Last Updated:	February 3, 2016
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	Enzyme Inhibitors
Diabetes Mellitus, Type 2	Hormones
Endocrine System Diseases	Hormones, Hormone Substitutes, and Hormone Antagonists
Glucose Metabolism Disorders	Hypoglycemic Agents
Metabolic Diseases	Incretins
Glipizide	Molecular Mechanisms of Pharmacological Action
Metformin	Pharmacologic Actions
Rosiglitazone	Physiological Effects of Drugs
Sitagliptin	Protease Inhibitors
Dipeptidyl-Peptidase IV Inhibitors	

ClinicalTrials.gov processed this record on April 13, 2016

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Results First Received: May 13, 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 Drug: Comparator: Placebo Drug: rosiglitazone Drug: metformin Drug: glipizide

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

Phase III

First Patient In: 29-Aug-06. Last Patient Enrolled: 23-Mar-07. Last Patient Last Visit: 27-May-08; 41 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 T2DM and inadequate glycemic control (HbA1c ≥7.5 and ≤11.0%) who were on stable doses of rosiglitazone (≥4 mg/day) and metformin (≥1500 mg/day) after an up to 20-week dose-titration and stabilization period were eligible to enter the 54-week study.

Reporting Groups

	Description
Sitagliptin 100 mg	The Sitagliptin 100 mg group includes data from patients randomized to receive treatment with 100 mg oral tablets of sitagliptin once daily (blinded) in addition to ongoing treatment with open-label rosiglitazone 4 mg oral tablets (4 to 8 mg/day) and open-label metformin 500 mg oral tablets (≥1500 mg/day).
Placebo	The Placebo group includes data from patients randomized to receive treatment with placebo to sitagliptin 100 mg tablet once daily (blinded) in addition to ongoing treatment with open-label rosiglitazone 4 mg oral tablets (4 to 8 mg/day) and open-label metformin 500 mg oral tablets (≥1500 mg/day).

Participant Flow: Overall Study

	Sitagliptin 100 mg	Placebo
STARTED	**170**	**92**
COMPLETED	**148**	**71**
NOT COMPLETED	**22**	**21**
Adverse Event	**4**	**2**
Lack of Efficacy	**0**	**4**
Lost to Follow-up	**2**	**0**
Physician Decision	**2**	**4**
Protocol Violation	**3**	**1**
Withdrawal by Subject	**9**	**8**
Patient Moved	**2**	**1**
Non-compliance with study procedures	**0**	**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 tablets of

	sitagliptin once daily (blinded) in addition to ongoing treatment with open-label rosiglitazone 4 mg oral tablets (4 to 8 mg/day) and open-label metformin 500 mg oral tablets (≥1500 mg/day).
Placebo	The Placebo group includes data from patients randomized to receive treatment with placebo to sitagliptin 100 mg tablet once daily (blinded) in addition to ongoing treatment with open-label rosiglitazone 4 mg oral tablets (4 to 8 mg/day) and open-label metformin 500 mg oral tablets (≥1500 mg/day).
Total	Total of all reporting groups

Baseline Measures

	Sitagliptin 100 mg	Placebo	Total
Number of Participants [units: participants]	170	92	262
Age [units: years] Mean (Standard Deviation)	54.4 (8.8)	54.8 (9.5)	54.5 (9.0)
Gender [units: participants]			
Female	74	37	111
Male	96	55	151
Race/Ethnicity [units: participants]			
White	82	51	133
Black	7	3	10
Hispanic	13	10	23
Asian	58	24	82
Other	10	4	14
HbA1c (Hemoglobin A1c) [units: Percent] Mean (Standard Deviation)	8.8 (1.0)	8.7 (1.0)	8.8 (1.0)

Outcome Measures

Hide All Outcome Measures

1. Primary: Change From Baseline in HbA1c (Hemoglobin A1C) at Week 18 [Time Frame: Baseline and 18 Weeks]

Measure Type	Primary
Measure Title	Change From Baseline in HbA1c (Hemoglobin A1C) at Week 18
Measure Description	HbA1c is measured as a percent. Thus, this change from baseline reflects the Week 18 HbA1c percent minus the Week 0 HbA1c percent.
Time Frame	Baseline and 18 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 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 18, the last non-baseline observed measurement was carried forward to Week 18.

Reporting Groups

	Description
Sitagliptin 100 mg	The Sitagliptin 100 mg group includes data from patients randomized to receive treatment with 100 mg oral tablets of sitagliptin once daily (blinded) in addition to ongoing treatment with open-label rosiglitazone 4 mg oral tablets (4 to 8 mg/day) and open-label metformin 500 mg oral tablets (≥1500 mg/day).
Placebo	The Placebo group includes data from patients randomized to receive treatment with placebo to sitagliptin 100 mg tablet once daily (blinded) in addition to ongoing treatment with open-label rosiglitazone 4 mg oral tablets (4 to 8 mg/day) and open-label metformin 500 mg oral tablets (≥1500 mg/day).

Measured Values

	Sitagliptin 100 mg	Placebo
Number of Participants Analyzed [units: participants]	**168**	**88**
Change From Baseline in HbA1c (Hemoglobin A1C) at Week 18 [units: Percent] Least Squares Mean (95% Confidence Interval)	**-1.03 (-1.17 to -0.90)**	**-0.31 (-0.50 to -0.13)**

Statistical Analysis 1 for Change From Baseline in HbA1c (Hemoglobin A1C) at Week 18

Groups [1]	All groups
Method [2]	ANCOVA
P Value [3]	<0.001
Mean Difference (Net) [4]	-0.72
Standard Deviation	(0.87)
95% Confidence Interval	-0.95 to -0.49

[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
[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 (Fasting Plasma Glucose) at Week 18 [Time Frame: Baseline and 18 Weeks]

Measure Type	Secondary
Measure Title	Change From Baseline in FPG (Fasting Plasma Glucose) at Week 18
Measure Description	Change from baseline at Week 18 is defined as Week 18 minus Week 0
Time Frame	Baseline and 18 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 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 18, the last non-baseline observed measurement was carried forward to Week 18.

Reporting Groups

	Description
Sitagliptin 100 mg	The Sitagliptin 100 mg group includes data from patients randomized to receive treatment with 100 mg oral tablets of sitagliptin once daily (blinded) in addition to ongoing treatment with open-label rosiglitazone 4 mg oral tablets (4 to 8 mg/day) and open-label metformin 500 mg oral tablets (≥1500 mg/day).
Placebo	The Placebo group includes data from patients randomized to receive treatment with placebo to sitagliptin 100 mg tablet once daily (blinded) in addition to ongoing treatment with open-label rosiglitazone 4 mg oral tablets (4 to 8 mg/day) and open-label metformin 500 mg oral tablets (≥1500 mg/day).

Measured Values

	Sitagliptin 100 mg	**Placebo**
Number of Participants Analyzed [units: participants]	**169**	**89**
Change From Baseline in FPG (Fasting Plasma Glucose) at Week 18 [units: mg/dL] Least Squares Mean (95% Confidence Interval)	**-30.7 (-35.5 to -26.0)**	**-11.7 (-18.3 to -5.1)**

Statistical Analysis 1 for Change From Baseline in FPG (Fasting Plasma Glucose) at Week 18

Groups [1]	All groups
Method [2]	ANCOVA
P Value [3]	<0.001
Mean Difference (Net) [4]	-19.0
Standard Deviation	(31.3)
95% Confidence Interval	-27.2 to -10.9

[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
[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 PMG (Post-meal Glucose) at Week 18 [Time Frame: Baseline and Week 18]

Measure Type	Secondary
Measure Title	Change From Baseline in 2-hour PMG (Post-meal Glucose) at Week 18
Measure Description	Change from baseline at Week 18 is defined as Week 18 minus Week 0
Time Frame	Baseline and Week 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.
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 18, the last non-baseline observed measurement was carried forward to Week 18.

Reporting Groups

	Description
Sitagliptin 100 mg	The Sitagliptin 100 mg group includes data from patients randomized to receive treatment with 100 mg oral tablets of sitagliptin once daily (blinded) in addition to ongoing treatment with open-label rosiglitazone 4 mg oral tablets (4 to 8 mg/day) and open-label metformin 500 mg oral tablets (≥1500 mg/day).
Placebo	The Placebo group includes data from patients randomized to receive treatment with placebo to sitagliptin 100 mg tablet once daily (blinded) in addition to ongoing treatment with open-label rosiglitazone 4 mg oral tablets (4 to 8 mg/day) and open-label metformin 500 mg oral tablets (≥1500 mg/day).

Measured Values

	Sitagliptin 100 mg	**Placebo**
Number of Participants Analyzed [units: participants]	**142**	**75**
Change From Baseline in 2-hour PMG (Post-meal Glucose) at Week 18 **[units: mg/dL]** **Least Squares Mean (95% Confidence Interval)**	**-59.9 (-67.1 to -52.6)**	**-22.0 (-32.1 to -12.0)**

Statistical Analysis 1 for Change From Baseline in 2-hour PMG (Post-meal Glucose) at Week 18

Groups [1]	All groups
Method [2]	ANCOVA

P Value [3]	<0.001
Mean Difference (Net) [4]	-37.9
Standard Deviation	(43.7)
95% Confidence Interval	-50.2 to -25.5

[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
[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.

4. Secondary: Change From Baseline in HbA1c (Hemoglobin A1C) at Week 54 [Time Frame: Baseline and Week 54]

Measure Type	Secondary
Measure Title	Change From Baseline in HbA1c (Hemoglobin A1C) at Week 54
Measure Description	HbA1c is measured as a percent. Thus, this change from baseline reflects the Week 54 HbA1c percent minus the Week 0 HbA1c percent.
Time Frame	Baseline and Week 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.
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 54, the last non-baseline observed measurement was carried forward to Week 54.

Reporting Groups

	Description
Sitagliptin 100 mg	The Sitagliptin 100 mg group includes data from patients randomized to receive treatment with 100 mg oral tablets of sitagliptin once daily (blinded) in addition to ongoing treatment with open-label rosiglitazone 4 mg oral tablets (4 to 8 mg/day) and open-label metformin 500 mg oral tablets (≥1500 mg/day).
Placebo	The Placebo group includes data from patients randomized to receive treatment with placebo to sitagliptin 100 mg tablet once daily (blinded) in addition to ongoing treatment with open-label rosiglitazone 4 mg oral tablets (4 to 8 mg/day) and open-label metformin 500 mg oral tablets (≥1500 mg/day).

Measured Values

	Sitagliptin 100 mg	**Placebo**
Number of Participants Analyzed		

[units: participants]	**168**	**88**
Change From Baseline in HbA1c (Hemoglobin A1C) at Week 54 **[units: Percent]** **Least Squares Mean (95% Confidence Interval)**	**-1.05 (-1.21 to -0.89)**	**-0.28 (-0.50 to -0.05)**

Statistical Analysis 1 for Change From Baseline in HbA1c (Hemoglobin A1C) at Week 54

Groups [1]	All groups
Method [2]	ANCOVA
P Value [3]	<0.001
Mean Difference (Net) [4]	-0.77
Standard Deviation	(1.04)
95% Confidence Interval	-1.04 to -0.50

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

5. Secondary: Change From Baseline in FPG (Fasting Plasma Glucose) at Week 54 [Time Frame: Baseline and Week 54]

Measure Type	Secondary
Measure Title	Change From Baseline in FPG (Fasting Plasma Glucose) at Week 54
Measure Description	Change from baseline at Week 54 is defined as Week 54 minus Week 0
Time Frame	Baseline and Week 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.
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 54, the last non-baseline observed measurement was carried forward to Week 54.

Reporting Groups

	Description
Sitagliptin 100 mg	The Sitagliptin 100 mg group includes data from patients randomized to receive treatment with 100 mg oral tablets of sitagliptin once daily (blinded) in addition to ongoing treatment with open-label rosiglitazone 4 mg oral tablets (4 to 8 mg/day) and open-label metformin 500 mg oral tablets (≥1500 mg/day).
Placebo	The Placebo group includes data from patients randomized to receive treatment with placebo to sitagliptin 100 mg tablet once daily (blinded) in addition to ongoing treatment with open-label rosiglitazone 4 mg oral tablets (4 to 8 mg/day) and open-label metformin 500 mg oral tablets (≥1500 mg/day).

Measured Values

	Sitagliptin 100 mg	Placebo
Number of Participants Analyzed [units: participants]	**169**	**89**
Change From Baseline in FPG (Fasting Plasma Glucose) at Week 54 [units: mg/dL] Least Squares Mean (95% Confidence Interval)	**-28.0 (-33.3 to -22.8)**	**-10.7 (-18.0 to -3.3)**

Statistical Analysis 1 for Change From Baseline in FPG (Fasting Plasma Glucose) at Week 54

Groups [1]	All groups
Method [2]	ANCOVA
P Value [3]	<0.001
Mean Difference (Net) [4]	-17.4
Standard Deviation	(34.6)
95% Confidence Interval	-26.4 to -8.4

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Model terms: treatment; baseline; prior anti-hyperglycemic 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.

6. Secondary: Change From Baseline in 2-hour PMG (Post-meal Glucose) at Week 54 [Time Frame: Baseline and Week 54]

Measure Type	Secondary
Measure Title	Change From Baseline in 2-hour PMG (Post-meal Glucose) at Week 54
Measure Description	Change from baseline at Week 54 is defined as Week 54 minus Week 0.
Time Frame	Baseline and Week 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.
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 54, the last non-baseline observed measurement was carried forward to Week 54.

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Measured Values

	Sitagliptin 100 mg	**Placebo**
Number of Participants Analyzed [units: participants]	**147**	**77**
Change From Baseline in 2-hour PMG (Post-meal Glucose) at Week 54 [units: mg/dL] Least Squares Mean (95% Confidence Interval)	**-50.7 (-59.1 to -42.4)**	**-16.6 (-28.2 to -5.0)**

Statistical Analysis 1 for Change From Baseline in 2-hour PMG (Post-meal Glucose) at Week 54

Groups [1]	All groups
Method [2]	ANCOVA
P Value [3]	<0.001
Mean Difference (Net) [4]	-34.1
Standard Deviation	(51.0)
95% Confidence Interval	-48.4 to -19.9

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

No text entered.

Serious Adverse Events

Hide Serious Adverse Events

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

Reporting Groups

	Description
Sitagliptin 100 mg Data Through Week 18	The Sitagliptin 100 mg group includes data from patients randomized to receive treatment with 100 mg oral tablets of sitagliptin once daily (blinded) in addition to ongoing treatment with open-label rosiglitazone 4 mg oral tablets (4 to 8 mg/day) and open-label metformin 500 mg oral tablets (≥1500 mg/day).
Placebo Data Through Week 18	The Placebo group includes data from patients randomized to receive treatment with placebo to sitagliptin 100 mg tablet once daily (blinded) in addition to ongoing treatment with open-label rosiglitazone 4 mg oral tablets (4 to 8 mg/day) and open-label metformin 500 mg oral tablets (≥1500 mg/day).
Sitagliptin 100 mg Data Through Week 54	No text entered.
Placebo Data Through Week 54	No text entered.

Serious Adverse Events

	Sitagliptin 100 mg Data Through Week 18	Placebo Data Through Week 18	Sitagliptin 100 mg Data Through Week 54	Placebo Data Through Week 54
Total, serious adverse events				
# participants affected	**2**	**2**	**14**	**4**
Cardiac disorders				
Any Cardiac Disorders [*1]				
# participants affected / at risk	**0/170 (0.00%)**	**0/92 (0.00%)**	**2/170 (1.18%)**	**0/92 (0.00%)**
Myocardial Infarction [*1]				
# participants affected / at risk	**0/170 (0.00%)**	**0/92 (0.00%)**	**2/170 (1.18%)**	**0/92 (0.00%)**
Ear and labyrinth disorders				
Any Ear And Labyrinth Disorders [*1]				
# participants affected / at risk	**0/170 (0.00%)**	**0/92 (0.00%)**	**1/170 (0.59%)**	**0/92 (0.00%)**
Vertigo [*1]				
# participants affected / at risk	**0/170 (0.00%)**	**0/92 (0.00%)**	**1/170 (0.59%)**	**0/92 (0.00%)**
Hepatobiliary disorders				
Any Hepatobiliary Disorders [*1]				
# participants affected / at risk	**0/170 (0.00%)**	**0/92 (0.00%)**	**1/170 (0.59%)**	**0/92 (0.00%)**
Biliary Colic [*1]				

# participants affected / at risk	0/170 (0.00%)	0/92 (0.00%)	1/170 (0.59%)	0/92 (0.00%)
Infections and infestations				
Any Infections And Infestations [*1]				
# participants affected / at risk	0/170 (0.00%)	0/92 (0.00%)	1/170 (0.59%)	0/92 (0.00%)
Urinary Tract Infection [*1]				
# participants affected / at risk	0/170 (0.00%)	0/92 (0.00%)	1/170 (0.59%)	0/92 (0.00%)
Injury, poisoning and procedural complications				
Any Injury, Poisoning And Procedural Complications [*1]				
# participants affected / at risk	0/170 (0.00%)	0/92 (0.00%)	0/170 (0.00%)	1/92 (1.09%)
Lower Limb Fracture [*1]				
# participants affected / at risk	0/170 (0.00%)	0/92 (0.00%)	0/170 (0.00%)	1/92 (1.09%)
Musculoskeletal and connective tissue disorders				
Any Musculoskeletal And Connective Tissue Disorders [*1]				
# participants affected / at risk	1/170 (0.59%)	0/92 (0.00%)	3/170 (1.76%)	0/92 (0.00%)
Intervertebral Disc Protrusion [*1]				
# participants affected / at risk	1/170 (0.59%)	0/92 (0.00%)	2/170 (1.18%)	0/92 (0.00%)
Pain In Extremity [*1]				
# participants affected / at risk	0/170 (0.00%)	0/92 (0.00%)	1/170 (0.59%)	0/92 (0.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
Any Neoplasms Benign, Malignant And Unspecified [*1]				
# participants affected / at risk	0/170 (0.00%)	1/92 (1.09%)	4/170 (2.35%)	2/92 (2.17%)
Astrocytoma Malignant [*1]				
# participants affected / at risk	0/170 (0.00%)	0/92 (0.00%)	0/170 (0.00%)	1/92 (1.09%)
Basal Cell Carcinoma [*1]				
# participants affected / at risk	0/170 (0.00%)	1/92 (1.09%)	1/170 (0.59%)	1/92 (1.09%)
Breast Cancer [*1]				
# participants affected / at risk	0/170 (0.00%)	0/92 (0.00%)	1/170 (0.59%)	0/92 (0.00%)
Neurilemmoma [*1]				
# participants affected / at risk	0/170 (0.00%)	0/92 (0.00%)	1/170 (0.59%)	0/92 (0.00%)
Prostate Cancer [*1]				
# participants affected / at risk	0/170 (0.00%)	0/92 (0.00%)	1/170 (0.59%)	0/92 (0.00%)
Nervous system disorders				
Any Nervous System Disorders [*1]				
# participants affected / at risk	0/170 (0.00%)	0/92 (0.00%)	2/170 (1.18%)	0/92 (0.00%)
Cerebrovascular Accident [*1]				
# participants affected / at risk	0/170 (0.00%)	0/92 (0.00%)	1/170 (0.59%)	0/92 (0.00%)
Diabetic Neuropathy [*1]				

# participants affected / at risk	0/170 (0.00%)	0/92 (0.00%)	1/170 (0.59%)	0/92 (0.00%)
Psychiatric disorders				
Any Psychiatric Disorders * 1				
# participants affected / at risk	0/170 (0.00%)	1/92 (1.09%)	0/170 (0.00%)	1/92 (1.09%)
Suicidal Ideation * 1				
# participants affected / at risk	0/170 (0.00%)	1/92 (1.09%)	0/170 (0.00%)	1/92 (1.09%)
Renal and urinary disorders				
Any Renal And Urinary Disorders * 1				
# participants affected / at risk	0/170 (0.00%)	0/92 (0.00%)	1/170 (0.59%)	0/92 (0.00%)
Renal Colic * 1				
# participants affected / at risk	0/170 (0.00%)	0/92 (0.00%)	1/170 (0.59%)	0/92 (0.00%)

* 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 Data Through Week 18	The Sitagliptin 100 mg group includes data from patients randomized to receive treatment with 100 mg oral tablets of sitagliptin once daily (blinded) in addition to ongoing treatment with open-label rosiglitazone 4 mg oral tablets (4 to 8 mg/day) and open-label metformin 500 mg oral tablets (≥1500 mg/day).
Placebo Data Through Week 18	The Placebo group includes data from patients randomized to receive treatment with placebo to sitagliptin 100 mg tablet once daily (blinded) in addition to ongoing treatment with open-label rosiglitazone 4 mg oral tablets (4 to 8 mg/day) and open-label metformin 500 mg oral tablets (≥1500 mg/day).
Sitagliptin 100 mg Data Through Week 54	No text entered.
Placebo Data Through Week 54	No text entered.

Other Adverse Events

	Sitagliptin 100 mg Data Through Week 18	Placebo Data Through Week 18	Sitagliptin 100 mg Data Through Week 54	Placebo Data Through Week 54
Total, other (not including serious) adverse events				
# participants affected	**20**	**14**	**70**	**35**

Gastrointestinal disorders				
Any Gastrointestinal Disorders * 1				
# participants affected / at risk	**0/170 (0.00%)**	**0/92 (0.00%)**	**8/170 (4.71%)**	**5/92 (5.43%)**
Diarrhoea * 1				
# participants affected / at risk	**0/170 (0.00%)**	**0/92 (0.00%)**	**8/170 (4.71%)**	**5/92 (5.43%)**
General disorders				
Any General Disorders And Administration Site Conditions * 1				
# participants affected / at risk	**0/170 (0.00%)**	**0/92 (0.00%)**	**15/170 (8.82%)**	**5/92 (5.43%)**
Oedema Peripheral * 1				
# participants affected / at risk	**0/170 (0.00%)**	**0/92 (0.00%)**	**15/170 (8.82%)**	**5/92 (5.43%)**
Infections and infestations				
Any Infections And Infestations * 1				
# participants affected / at risk	**20/170 (11.76%)**	**10/92 (10.87%)**	**46/170 (27.06%)**	**15/92 (16.30%)**
Nasopharyngitis * 1				
# participants affected / at risk	**10/170 (5.88%)**	**4/92 (4.35%)**	**18/170 (10.59%)**	**9/92 (9.78%)**
Upper Respiratory Tract Infection * 1				
# participants affected / at risk	**10/170 (5.88%)**	**6/92 (6.52%)**	**28/170 (16.47%)**	**6/92 (6.52%)**
Musculoskeletal and connective tissue disorders				
Any Musculoskeletal And Connective Tissue Disorders * 1				
# participants affected / at risk	**0/170 (0.00%)**	**5/92 (5.43%)**	**7/170 (4.12%)**	**5/92 (5.43%)**
Back Pain * 1				
# participants affected / at risk	**0/170 (0.00%)**	**5/92 (5.43%)**	**7/170 (4.12%)**	**5/92 (5.43%)**
Nervous system disorders				
Any Nervous System Disorders * 1				
# participants affected / at risk	**0/170 (0.00%)**	**0/92 (0.00%)**	**14/170 (8.24%)**	**8/92 (8.70%)**
Dizziness * 1				
# participants affected / at risk	**0/170 (0.00%)**	**0/92 (0.00%)**	**6/170 (3.53%)**	**5/92 (5.43%)**
Headache * 1				
# participants affected / at risk	**0/170 (0.00%)**	**0/92 (0.00%)**	**10/170 (5.88%)**	**4/92 (4.35%)**
Any Respiratory, Thoracic And Mediastinal Disorders * 1				
# participants affected / at risk	**0/170 (0.00%)**	**0/92 (0.00%)**	**7/170 (4.12%)**	**7/92 (7.61%)**
Respiratory, thoracic and mediastinal disorders				
Cough * 1				
# participants affected / at risk	**0/170 (0.00%)**	**0/92 (0.00%)**	**7/170 (4.12%)**	**7/92 (7.61%)**

* 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

Non-serious adverse event results represent those events included in the primary safety analysis for this study (events occurred prior to initiation of glycemic rescue therapy). Site 0520039 was non-compliant with GDP, data was removed from 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:

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Publications automatically indexed to this study by ClinicalTrials.gov Identifier (NCT Number):

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Responsible Party:	Merck Sharp & Dohme Corp.
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