Safety/Efficacy of Sitagliptin in Patient w/ Type 2 Diabetes (0431-801)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

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

ClinicalTrials.gov Identifier:
NCT00541775

First received: October 5, 2007
Last updated: August 21, 2015
Last verified: August 2015
History of Changes

Purpose

The purpose of this study is to test the safety and effectiveness of sitagliptin in patients with type 2 diabetes.

Condition	Intervention	Phase
Type 2 Diabetes Mellitus	Drug: Sitagliptin Drug: Comparator: Rosiglitazone Drug: Comparator: Placebo Drug: Comparator: Metformin	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, Placebo and Active Controlled, Randomized Study to Evaluate the Safety and Efficacy of the Addition of Sitagliptin 100 mg Once Daily in Patients With Type 2 Diabetes With Inadequate Glycemic Control on Metformin Monotherapy

Resource links provided by NLM:

MedlinePlus related topics: Diabetes Type 2

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

U.S. FDA Resources

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

Primary Outcome Measures:

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

  A1C is measured as percent. Thus, this change from baseline reflects the Week 18 A1C percent minus the Week 0 A1C percent. The study hypothesis comparison was between sitagliptin versus placebo.

Secondary Outcome Measures:

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

  The change from baseline is the Week 18 FPG minus the Week 0 FPG.

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

  The change from baseline is the Week 18 PMG minus the Week 0 PMG.

Enrollment:	273
Study Start Date:	June 2006
Study Completion Date:	March 2007
Primary Completion Date:	March 2007 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: Sitagliptin sitagliptin 100 mg	Drug: Sitagliptin Sitagliptin 100 mg administered as one oral tablet once daily in the morning for up to 18 weeks. Other Name: Januvia Drug: Comparator: Metformin Open-label metformin was supplied by the Sponsor as 500, 850, or 1000 mg oral tablets administered at a daily dose of >= 1500 mg.
Active Comparator: Rosiglitazone rosiglitazone 8 mg	Drug: Comparator: Rosiglitazone Rosiglitazone 8 mg administered as two 4 mg capsules once daily in the morning for up to 18 weeks. Other Name: Avandia Drug: Comparator: Metformin Open-label metformin was supplied by the Sponsor as 500, 850, or 1000 mg oral tablets administered at a daily dose of >= 1500 mg.
Placebo Comparator: Placebo placebo	Drug: Comparator: Placebo placebo - administered as one placebo tablet to match Sitagliptin 100 mg and two placebo capsules to match rosiglitazone 4 mg once daily in the morning for up to 18 weeks. Drug: Comparator: Metformin Open-label metformin was supplied by the Sponsor as 500, 850, or 1000 mg oral tablets administered at a daily dose of >= 1500 mg.

Eligibility

Ages Eligible for Study:	18 Years to 75 Years
Genders Eligible for Study:	Both
Accepts Healthy Volunteers:	Yes

Criteria

Inclusion Criteria:

- Patient has Type 2 diabetes
- Currently taking metformin >1500 mg/day for at least 10 weeks
- Male or female

Exclusion Criteria:

- Patient has peripheral edema
- History of type 1 diabetes

- Patient required insulin within prior 8 weeks
- Have participated or are currently participating in another study with an investigational compound or device within 12 weeks of starting this study
- Participating in a weight loss program

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: NCT00541775

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:

Scott R, Loeys T, Davies MJ, Engel SS; Sitagliptin Study 801 Group. Efficacy and safety of sitagliptin when added to ongoing metformin therapy in patients with type 2 diabetes. Diabetes Obes Metab. 2008 Sep;10(10):959-69. doi: 10.1111/j.1463-1326.2007.00839.x. Epub 2008 Jan 14.

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ClinicalTrials.gov Identifier:	NCT00541775 History of Changes
Other Study ID Numbers:	0431-801 2007_623
Study First Received:	October 5, 2007
Results First Received:	May 17, 2010
Last Updated:	August 21, 2015
Health Authority:	Belgium: Federal Agency for Medicines and Health Products, FAMHP

Additional relevant MeSH terms:

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

ClinicalTrials.gov processed this record on April 13, 2016

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Results First Received: May 17, 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:	Type 2 Diabetes Mellitus
Interventions:	Drug: Sitagliptin Drug: Comparator: Rosiglitazone Drug: Comparator: Placebo Drug: Comparator: Metformin

Participant Flow

Hide Participant Flow

Recruitment Details

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

First Patient In: 16-June-2006. Last Patient Last Visit: 2-March-2007. 13 medical clinics in 3 countries in Europe and 23 in 4 countries in the rest of the world

Pre-Assignment Details

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

Patients 18-75 years of age with type 2 diabetes mellitus (T2DM) who were taking metformin monotherapy at a stable dose of ≥ 1500 mg/day for at least 10 weeks and had inadequate glycemic control (hemoglobin A1C ≥ 7.0% and ≤11%) were eligible to participate.

Reporting Groups

	Description
Sitagliptin	The Sitagliptin group includes data from patients randomized to receive treatment with oral tablets of sitagliptin 100 mg and placebo matching rosiglitazone q.d. (once-daily) with metformin (≥1500 mg/day).
Rosiglitazone	The Rosiglitazone group includes data from patients randomized to receive treatment with oral tablets of rosiglitazone 8 mg and placebo matching sitagliptin q.d. in combination with metformin (≥1500 mg/day).
Placebo	The Placebo group includes data from patients randomized to receive treatment with oral tablets of placebo matching sitagliptin and placebo matching rosiglitazone q.d. with metformin (≥1500 mg/day).

Participant Flow: Overall Study

	Sitagliptin	Rosiglitazone	Placebo
STARTED	94	87	92
COMPLETED	85	85	84
NOT COMPLETED	9	2	8
Adverse Event	3	2	1
Lack of Efficacy	0	0	3
Lost to Follow-up	0	0	2
Protocol Violation	1	0	0
Withdrawal by Subject and Other	5	0	2

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	The Sitagliptin group includes data from patients randomized to receive treatment with oral tablets of sitagliptin 100 mg and placebo matching rosiglitazone q.d. (once-daily) with metformin (≥1500 mg/day).
Rosiglitazone	The Rosiglitazone group includes data from patients randomized to receive treatment with oral tablets of rosiglitazone 8 mg and placebo matching sitagliptin q.d. in combination with metformin (≥1500 mg/day).
Placebo	The Placebo group includes data from patients randomized to receive treatment with oral tablets of placebo matching sitagliptin and placebo matching rosiglitazone q.d. with metformin (≥1500 mg/day).
Total	Total of all reporting groups

Baseline Measures

	Sitagliptin	Rosiglitazone	Placebo	Total
Number of Participants [units: participants]	94	87	92	273
Age [units: years] Mean (Standard Deviation)	55.2 (9.8)	54.8 (10.5)	55.3 (9.3)	55.1 (9.8)
Gender [units: participants]				
Female	42	32	38	112
Male	52	55	54	161
Race/Ethnicity, Customized [units: participants]				
White	57	51	56	164
Black	0	1	0	1
Asian	36	33	36	105
Other	1	2	0	3
Fasting Plasma Glucose (FPG) [units: mg/dL] Mean (Standard Deviation)	157.5 (31.4)	156.9 (31.6)	160.0 (37.4)	158.1 (33.5)
Hemoglobin A1C (A1C) [units: Percent of glycosylated hemoglobin (A1C)] Mean (Standard Deviation)	7.8 (1.0)	7.7 (0.8)	7.7 (0.9)	7.7 (0.9)

Outcome Measures

Hide All Outcome Measures

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

Measure Type	Primary
Measure Title	Hemoglobin A1C (A1C) at Week 18
Measure Description	A1C is measured as percent. Thus, this change from baseline reflects the Week 18 A1C percent minus the Week 0 A1C percent. The study hypothesis comparison was between sitagliptin versus placebo.
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 all patients treated population included all patients who took at least one dose of study medication and had both a baseline measurement and at least one post-randomization measurement for this outcome. Missing data were imputed using the last observation carried forward (LOCF) method.

Reporting Groups

	Description
Sitagliptin	The Sitagliptin group includes data from patients randomized to receive treatment with oral tablets of sitagliptin 100 mg and placebo matching rosiglitazone q.d. (once-daily) with metformin (≥1500 mg/day).
Rosiglitazone	The Rosiglitazone group includes data from patients randomized to receive treatment with oral tablets of rosiglitazone 8 mg and placebo matching sitagliptin q.d. in combination with metformin (≥1500 mg/day).
Placebo	The Placebo group includes data from patients randomized to receive treatment with oral tablets of placebo matching sitagliptin and placebo matching rosiglitazone q.d. with metformin (≥1500 mg/day).

Measured Values

	Sitagliptin	Rosiglitazone	Placebo
Number of Participants Analyzed [units: participants]	**91**	**87**	**88**
Hemoglobin A1C (A1C) at Week 18 [units: Percent of glycosylated hemoglobin (A1C)] Least Squares Mean (95% Confidence Interval)	**-0.73 (-0.87 to -0.60)**	**-0.79 (-0.92 to -0.65)**	**-0.22 (-0.36 to -0.08)**

Statistical Analysis 1 for Hemoglobin A1C (A1C) at Week 18

Groups [1]	Sitagliptin vs. Placebo
Method [2]	ANCOVA
P Value [3]	<=0.001
Mean Difference (Net) [4]	-0.51
Standard Error of the mean	(0.1)
95% Confidence Interval	-0.70 to -0.32

[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:
	Analysis of covariance with a term for treatment, and a covariate for baseline value.
[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: Fasting Plasma Glucose (FPG) at Week 18 [Time Frame: Baseline and 18 Weeks]

Measure Type	Secondary
Measure Title	Fasting Plasma Glucose (FPG) at Week 18
Measure Description	The change from baseline is the Week 18 FPG minus the Week 0 FPG.
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 all patients treated population included all patients who took at least one dose of study medication and had both a baseline measurement and at least one post-randomization measurement for this outcome. Missing data were imputed using the last observation carried forward (LOCF) method.

Reporting Groups

	Description
Sitagliptin	The Sitagliptin group includes data from patients randomized to receive treatment with oral tablets of sitagliptin 100 mg and placebo matching rosiglitazone q.d. (once-daily) with metformin (≥1500 mg/day).
Rosiglitazone	The Rosiglitazone group includes data from patients randomized to receive treatment with oral tablets of rosiglitazone 8 mg and placebo matching sitagliptin q.d. in combination with metformin (≥1500 mg/day).
Placebo	The Placebo group includes data from patients randomized to receive treatment with oral tablets of placebo matching sitagliptin and placebo matching rosiglitazone q.d. with metformin (≥1500 mg/day).

Measured Values

	Sitagliptin	**Rosiglitazone**	**Placebo**
Number of Participants Analyzed [units: participants]	**92**	**87**	**89**
Fasting Plasma Glucose (FPG) at Week 18 [units: mg/dL] Least Squares Mean (95% Confidence Interval)	**-11.7 (-18.6 to -4.9)**	**-24.5 (-31.6 to -17.5)**	**6.1 (-0.8 to 13.1)**

Statistical Analysis 1 for Fasting Plasma Glucose (FPG) at Week 18

Groups [1]	Sitagliptin vs. Placebo
Method [2]	ANCOVA
P Value [3]	<=0.001
Mean Difference (Net) [4]	-17.8
Standard Error of the mean	(5)
95% Confidence Interval	-27.6 to -8.1

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Analysis of covariance with a term for treatment, and a covariate for baseline value.
[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: 2-hour Post-meal Glucose (PMG) at Week 18 [Time Frame: Baseline and 18 Weeks]

Measure Type	Secondary
Measure Title	2-hour Post-meal Glucose (PMG) at Week 18
Measure Description	The change from baseline is the Week 18 PMG minus the Week 0 PMG.
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 all patients treated population included all patients who took at least one dose of study medication and had both a baseline measurement and at least one post-randomization measurement for this outcome. Missing data were imputed using the last observation carried forward (LOCF) method.

Reporting Groups

	Description
Sitagliptin	The Sitagliptin group includes data from patients randomized to receive treatment with oral tablets of sitagliptin 100 mg and placebo matching rosiglitazone q.d. (once-daily) with metformin (≥1500 mg/day).
Rosiglitazone	The Rosiglitazone group includes data from patients randomized to receive treatment with oral tablets of rosiglitazone 8 mg and placebo matching sitagliptin q.d. in combination with metformin (≥1500 mg/day).
Placebo	The Placebo group includes data from patients randomized to receive treatment with oral tablets of placebo matching sitagliptin and placebo matching rosiglitazone q.d. with metformin (≥1500 mg/day).

Measured Values

	Sitagliptin	**Rosiglitazone**	**Placebo**
Number of Participants Analyzed [units: participants]	**80**	**76**	**78**
2-hour Post-meal Glucose (PMG) at Week 18 [units: mg/dL] Least Squares Mean (95% Confidence Interval)	**-35.4 (-46.3 to -24.5)**	**-51.3 (-62.5 to -40.1)**	**-4.9 (-16.0 to 6.1)**

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

Groups [1]	Sitagliptin vs. Placebo
Method [2]	ANCOVA
P Value [3]	<=0.001
Mean Difference (Net) [4]	-30.5
Standard Error of the mean	(7.9)
95% Confidence Interval	-46.0 to -15.0

[1]	Additional details about the analysis, such as null hypothesis and power calculation:

	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Analysis of covariance with a term for treatment, and a covariate for baseline value.
[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 to 18
Additional Description	Safety tables are based on the All Patients as Treated (APaT) population that includes all patients who took at least one dose of study drug. One patient in the placebo group did not take any study drug. Thus, for the placebo group 92 patients are reported in the baseline characteristics and 91 patients are reported in the AE summary.

Reporting Groups

	Description
Sitagliptin	The Sitagliptin group includes data from patients randomized to receive treatment with oral tablets of sitagliptin 100 mg and placebo matching rosiglitazone q.d. (once-daily) with metformin (≥1500 mg/day).
Rosiglitazone	The Rosiglitazone group includes data from patients randomized to receive treatment with oral tablets of rosiglitazone 8 mg and placebo matching sitagliptin q.d. in combination with metformin (≥1500 mg/day).
Placebo	The Placebo group includes data from patients randomized to receive treatment with oral tablets of placebo matching sitagliptin and placebo matching rosiglitazone q.d. with metformin (≥1500 mg/day).

Serious Adverse Events

	Sitagliptin	Rosiglitazone	Placebo
Total, serious adverse events			
# participants affected / at risk	**5/94 (5.32%)**	**5/87 (5.75%)**	**5/91 (5.49%)**
Cardiac disorders			
Angina unstable * 1			
# participants affected / at risk	**1/94 (1.06%)**	**0/87 (0.00%)**	**0/91 (0.00%)**
Coronary artery disease * 1			
# participants affected / at risk	**1/94 (1.06%)**	**0/87 (0.00%)**	**0/91 (0.00%)**
Injury, poisoning and procedural complications			
Intentional overdose * 1			
# participants affected / at risk	**0/94 (0.00%)**	**1/87 (1.15%)**	**0/91 (0.00%)**
Overdose * 1			

# participants affected / at risk	2/94 (2.13%)	3/87 (3.45%)	2/91 (2.20%)
Skin laceration * 1			
# participants affected / at risk	1/94 (1.06%)	0/87 (0.00%)	0/91 (0.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Prostate cancer * 1			
# participants affected / at risk	0/94 (0.00%)	0/87 (0.00%)	1/91 (1.10%)
Nervous system disorders			
Syncope * 1			
# participants affected / at risk	0/94 (0.00%)	1/87 (1.15%)	0/91 (0.00%)
Reproductive system and breast disorders			
Endometrial hyperplasia * 1			
# participants affected / at risk	0/94 (0.00%)	0/87 (0.00%)	1/91 (1.10%)
Respiratory, thoracic and mediastinal disorders			
Asthma * 1			
# participants affected / at risk	0/94 (0.00%)	0/87 (0.00%)	1/91 (1.10%)

* Events were collected by non-systematic assessment

1 Term from vocabulary, MedDRA 11.1

Other Adverse Events

Hide Other Adverse Events

Time Frame	Weeks 0 to 18
Additional Description	Safety tables are based on the All Patients as Treated (APaT) population that includes all patients who took at least one dose of study drug. One patient in the placebo group did not take any study drug. Thus, for the placebo group 92 patients are reported in the baseline characteristics and 91 patients are reported in the AE summary.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
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Other Adverse Events

	Sitagliptin	Rosiglitazone	Placebo
Total, other (not including serious) adverse events			

# participants affected / at risk	**5/94 (5.32%)**	**1/87 (1.15%)**	**0/91 (0.00%)**
Investigations			
Blood glucose increased * 1			
# participants affected / at risk	**5/94 (5.32%)**	**1/87 (1.15%)**	**0/91 (0.00%)**

* Events were collected by non-systematic assessment
1 Term from vocabulary, MedDRA 11.1

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:

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