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Home > Find Studies > Search Results > Study Record Detail Text Size

Trial record **1 of 1** for: NCT00541450

Previous Study | Return to List | Next Study

A Study to Evaluate the Efficacy and Safety of Sitagliptin and MK0431A in Comparison to a Commonly Used Medication in Patients With Type 2 Diabetes (0431-068)(COMPLETED)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

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

ClinicalTrials.gov Identifier:
NCT00541450

First received: October 5, 2007
Last updated: May 4, 2015
Last verified: May 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 evaluate the efficacy and safety of sitagliptin and MK0431A in comparison to a commonly used medication in patients with type 2 diabetes.

Condition	Intervention	Phase
Type 2 Diabetes Mellitus	Drug: Comparator: sitagliptin phosphate (sitagliptin) Drug: sitagliptin phosphate (+) metformin hydrochloride Drug: Comparator: pioglitazone Drug: Matching placebo to pioglitazone Drug: Matching placebo to sitagliptin Drug: Matching Placebo to Sita/Met FDC	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, Active-Comparator (Pioglitazone) Controlled Clinical Trial to Study the Efficacy and Safety of Sitagliptin and MK0431A (A Fixed-Dose Combination Tablet of Sitagliptin and Metformin) in Patients With Type 2 Diabetes Mellitus

Resource links provided by NLM:

MedlinePlus related topics: Diabetes Type 2

Drug Information available for: Metformin Metformin hydrochloride Pioglitazone Pioglitazone hydrochloride Sitagliptin Sitagliptin phosphate

U.S. FDA Resources

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

Primary Outcome Measures:

- Change in Hemoglobin A1c (A1C) in the Sita/Met Fixed-Dose Combination (FDC) or Pioglitazone Groups at 40 Weeks [Time Frame: Baseline to 40 weeks] [Designated as safety issue: No]

  The change in A1C, compared to baseline for the Sita/Met FDC and the pioglitazone groups at Week 40. A1C represents percentage of glycosylated hemoglobin.

- Change in Hemoglobin A1c (A1C) in Participants Treated With Sitagliptin or Pioglitazone at 12 Weeks [Time Frame: Baseline to 12 weeks] [Designated as safety issue: No]

  The change in A1C compared to baseline was measured for the participants treated with sitagliptin or pioglitazone at Week 12. Sitagliptin was the only intervention administered to the Sita/Met FDC group during this phase. A1c represents percentage of glycosylated hemoglobin.

Secondary Outcome Measures:

- Change in 2-hour Postprandial Glucose (PMG) in the Sita/Met FDC or Pioglitazone Groups at 40 Weeks [Time Frame: Baseline and 40 weeks] [Designated as safety issue: No]

  The change in PMG compared to baseline was measured using the Meal Tolerance Test (MTT) for the Sita/Met FDC and the pioglitazone groups at Week 40.

- Change in 2-hour Postprandial Glucose (PMG) in Participants Treated With Sitagliptin or Pioglitazone at 12 Weeks [Time Frame: Baseline to 12 weeks] [Designated as safety issue: No]

  The change in PMG compared to baseline was measured using the Meal Tolerance Test (MTT) for the participants treated with Sitagliptin or Pioglitazone at Week 12. Sitagliptin was the only intervention administered to the Sita/Met FDC group during this phase. To calculate Least Squares, the ANCOVA model included a term for treatment and the baseline value as a covariate.

- Change in Fasting Plasma Glucose (FPG) in the Sita/Met FDC or Pioglitazone Groups at 40 Weeks [Time Frame: Baseline and 40 weeks] [Designated as safety issue: No]

  The change in FPG compared to baseline was measured for the Sita/Met FDC and the pioglitazone groups at Week 40.

- Change in Fasting Plasma Glucose (FPG) in Participants Treated With Sitagliptin or Pioglitazone at 12 Weeks [Time Frame: Baseline to 12 weeks] [Designated as safety issue: No]

  The change in FPG compared to baseline was measured for the participants treated with sitagliptin or pioglitazone at Week 12. Sitagliptin was the only intervention administered to the Sita/Met FDC group during this phase. To calculate Least Squares, the ANCOVA model included a term for treatment and the baseline value as a covariate.

Enrollment:	492
Study Start Date:	January 2008
Study Completion Date:	January 2010
Primary Completion Date:	January 2010 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: Sita/Met FDC In Phase A (Treatment Day 1 to Week 12), participants were administered 100 mg once daily (q.d.) of sitagliptin and matching placebo to 15 mg pioglitazone q.d. for 6 weeks followed by matching placebo to 30 mg pioglitazone for the next 6 weeks. In Phase B (Treatment Week 12-Week 40), participants were switched to the Sita/Met Fixed-Dose Combination (FDC) at a dose of 50/500 mg twice a day (b.i.d.), which was increased to 50/1000 mg b.i.d. over a period of 4 weeks; as well as matching placebo to 45 mg pioglitazone.	Drug: Comparator: sitagliptin phosphate (sitagliptin) sitagliptin 100 mg tablet q.d. orally for a 12-wk treatment period Other Name: MK0431, Januvia™ Drug: sitagliptin phosphate (+) metformin hydrochloride sitagliptin/metformin HCl (Sita/Met) 50/500 mg b.i.d. orally and then 50/1000 mg b.i.d. orally for a 28-wk treatment period Other Name: MK-0431A, Janumet™ Drug: Matching placebo to pioglitazone matching placebo to pioglitazone tablet q.d. orally, for a 40-wk treatment period. Participants were administered matching placebo the 15 mg pioglitazone q.d. orally for 6 weeks, followed by matching placebo

	to 30 mg pioglitazone q.d orally for 6 weeks, followed by matching placebo to 45 mg pioglitazone q.d. orally, up to 40 weeks.
Active Comparator: Pioglitazone In Phase A (Treatment Day 1 up to Week 12), randomized participants in the pioglitazone group were administered 15 mg q.d. of pioglitazone and matching placebo to sitagliptin. At Week 6, participants were up-titrated to 30 mg pioglitazone q.d. In Phase B (Treatment Week 12 to Week 40), participants were administered 45 mg pioglitazone q.d.; as well as matching placebo to Sita/Met FDC (50/500 increased to 50/1000 b.i.d. after 4 weeks).	Drug: Comparator: pioglitazone pioglitazone 15 mg tablet q.d. orally for 6 weeks, followed by 30 mg q.d orally for 6 weeks, followed by 45 mg q.d. orally, up to 40 weeks. Other Name: Actos® Drug: Matching placebo to sitagliptin matching placebo to sitagliptin q.d., orally for a 12-wk treatment period. Drug: Matching Placebo to Sita/Met FDC matching placebo to Sita/Met FDC - 50/500 mg b.i.d. for 4 weeks and then 50/1000 mg b.i.d. orally for a 28-wk treatment period (Week 12 to Week 40).

Eligibility

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

Criteria

Inclusion Criteria:

- Patients between the ages of 18 and 78 with type 2 diabetes mellitus
- Patient has not been on any antihyperglycemic agent (Insulin or oral) in the last 3 months

Exclusion Criteria:

- Patient has a history of type 1 diabetes mellitus or a history of ketoacidosis
- Patient has previously been treated with sitagliptin or has previously been in a study using a DPP-4 inhibitor

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: NCT00541450

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:

Pérez-Monteverde A, Seck T, Xu L, Lee MA, Sisk CM, Williams-Herman DE, Engel SS, Kaufman KD, Goldstein BJ. Efficacy and safety of

sitagliptin and the fixed-dose combination of sitagliptin and metformin vs. pioglitazone in drug-naïve patients with type 2 diabetes. Int J Clin Pract. 2011 Sep;65(9):930-8. doi: 10.1111/j.1742-1241.2011.02749.x.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00541450 History of Changes
Other Study ID Numbers:	0431-068 2007_501
Study First Received:	October 5, 2007
Results First Received:	January 13, 2011
Last Updated:	May 4, 2015
Health Authority:	United States: Food and Drug Administration

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
Metformin	Molecular Mechanisms of Pharmacological Action
Pioglitazone	Pharmacologic Actions
Sitagliptin	Physiological Effects of Drugs
Dipeptidyl-Peptidase IV Inhibitors	Protease Inhibitors

ClinicalTrials.gov processed this record on April 13, 2016

TO TOP

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

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Trial record **1 of 1** for: NCT00541450
Previous Study | Return to List | Next Study

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Results First Received: January 13, 2011

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: Comparator: sitagliptin phosphate (sitagliptin) Drug: sitagliptin phosphate (+) metformin hydrochloride Drug: Comparator: pioglitazone Drug: Matching placebo to pioglitazone Drug: Matching placebo to sitagliptin Drug: Matching Placebo to Sita/Met FDC

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
No text entered.

Pre-Assignment Details

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

No text entered.

Reporting Groups

	Description
Sita/Met FDC	In Phase A (Treatment Day 1 up to Week 12), participants were administered 100 mg once daily (q.d.) of sitagliptin and matching placebo to pioglitazone. In Phase B (Treatment Week 12 to Week 40), participants that continued were switched to the Sita/Met Fixed-Dose Combination (FDC) at a dose of 50/500 mg twice a day (b.i.d.), which was increased to 50/1000 mg b.i.d. over a period of 4 weeks.
Pioglitazone	In Phase A (Treatment Day 1 up to Week 12), participants in the pioglitazone group were administered 15 mg once daily (q.d.) of pioglitazone and matching placebo to sitagliptin. At Week 6, all participants were administered 30 mg q.d. pioglitazone. In Phase B (Treatment Week 12 to Week 40), participants that continued were administered 45 mg pioglitazone once daily (q.d.).

Participant Flow for 2 periods

Period 1: Phase A

	Sita/Met FDC	Pioglitazone
STARTED	**244**	**248**
COMPLETED	**224**	**231**
NOT COMPLETED	**20**	**17**
Adverse Event	**3**	**0**
Creatinine/CrCl -Increase in creatinine	**0**	**2**
Hyperglycemia	**0**	**1**
Lost to Follow-up	**6**	**4**
Physician Decision	**2**	**0**
Protocol Violation	**2**	**3**
Withdrawal by Subject	**7**	**7**

Period 2: Phase B

	Sita/Met FDC	Pioglitazone
STARTED	**224**	**231**
COMPLETED	**187**	**200**
NOT COMPLETED	**37**	**31**
Adverse Event	**6**	**6**
Hyperglycemia	**10**	**9**
Lost to Follow-up	**6**	**4**
Physician Decision	**4**	**2**
Pregnancy	**0**	**1**
Protocol Violation	**3**	**3**
Withdrawal by Subject	**8**	**6**

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
Sita/Met FDC	In Phase A (Treatment Day 1 up to Week 12), participants were administered 100 mg once daily (q.d.) of sitagliptin and matching placebo to pioglitazone. In Phase B (Treatment Week 12 to Week 40), participants that continued were switched to the Sita/Met Fixed-Dose Combination (FDC) at a dose of 50/500 mg twice a day (b.i.d.), which was increased to 50/1000 mg b.i.d. over a period of 4 weeks.
Pioglitazone	In Phase A (Treatment Day 1 up to Week 12), participants in the pioglitazone group were administered 15 mg once daily (q.d.) of pioglitazone and matching placebo to sitagliptin. At Week 6, all participants were administered 30 mg q.d. pioglitazone. In Phase B (Treatment Week 12 to Week 40), participants that continued were administered 45 mg pioglitazone once daily (q.d.).
Total	Total of all reporting groups

Baseline Measures

	Sita/Met FDC	**Pioglitazone**	**Total**
Number of Participants [units: participants]	**244**	**248**	**492**
Age [units: years] Mean (Standard Deviation)	**50.5 (10.9)**	**51.7 (10.1)**	**51.1 (10.5)**
Gender [units: participants]			
Female	**92**	**100**	**192**
Male	**152**	**148**	**300**

Outcome Measures

Hide All Outcome Measures

1. Primary: Change in Hemoglobin A1c (A1C) in the Sita/Met Fixed-Dose Combination (FDC) or Pioglitazone Groups at 40 Weeks [Time Frame: Baseline to 40 weeks]

Measure Type	Primary
Measure Title	Change in Hemoglobin A1c (A1C) in the Sita/Met Fixed-Dose Combination (FDC) or Pioglitazone Groups at 40 Weeks
Measure Description	The change in A1C, compared to baseline for the Sita/Met FDC and the pioglitazone groups at Week 40. A1C

	represents percentage of glycosylated hemoglobin.
Time Frame	Baseline to 40 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.
All randomized participants who (1) took at least one dose of study medication; i.e., sitagliptin or pioglitazone 15/30 mg q.d. for the Weeks 0-12, and Sita/Met FDC or pioglitazone 45 mg q.d. for the Weeks 0-40 (Phase A and Phase B); and (2) had a baseline measurement and at least one on-treatment measurement for A1C.

Reporting Groups

	Description
Sita/Met FDC	In Phase A (Treatment Day 1 up to Week 12), participants were administered 100 mg once daily (q.d.) of sitagliptin and matching placebo to pioglitazone. In Phase B (Treatment Week 12 to Week 40), participants that continued were switched to the Sita/Met Fixed-Dose Combination (FDC) at a dose of 50/500 mg twice a day (b.i.d.), which was increased to 50/1000 mg b.i.d. over a period of 4 weeks.
Pioglitazone	In Phase A (Treatment Day 1 up to Week 12), participants in the pioglitazone group were administered 15 mg once daily (q.d.) of pioglitazone and matching placebo to sitagliptin. At Week 6, all participants were administered 30 mg q.d. pioglitazone. In Phase B (Treatment Week 12 to Week 40), participants that continued were administered 45 mg pioglitazone once daily (q.d.).

Measured Values

	Sita/Met FDC	**Pioglitazone**
Number of Participants Analyzed [units: participants]	**218**	**222**
Change in Hemoglobin A1c (A1C) in the Sita/Met Fixed-Dose Combination (FDC) or Pioglitazone Groups at 40 Weeks [units: percentage of glycosylated hemoglobin] Least Squares Mean (95% Confidence Interval)	**-1.75 (-1.92 to -1.59)**	**-1.38 (-1.55 to -1.21)**

Statistical Analysis 1 for Change in Hemoglobin A1c (A1C) in the Sita/Met Fixed-Dose Combination (FDC) or Pioglitazone Groups at 40 Weeks

Groups [1]	All groups
Method [2]	ANCOVA
P Value [3]	0.002

[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:
	For Least Squares Mean, the ANCOVA model included a term for treatment and the baseline value as a covariate.
[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.

2. Primary: Change in Hemoglobin A1c (A1C) in Participants Treated With Sitagliptin or Pioglitazone at 12 Weeks [Time Frame: Baseline to 12 weeks]

Measure Type	Primary
Measure Title	Change in Hemoglobin A1c (A1C) in Participants Treated With Sitagliptin or Pioglitazone at 12 Weeks
Measure Description	The change in A1C compared to baseline was measured for the participants treated with sitagliptin or pioglitazone at Week 12. Sitagliptin was the only intervention administered to the Sita/Met FDC group during this phase. A1c represents percentage of glycosylated hemoglobin.
Time Frame	Baseline to 12 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.
All randomized participants who (1) took at least one dose of study medication; i.e., sitagliptin or pioglitazone 15/30 mg q.d. for the Weeks 0-12; and (2) had a baseline measurement and at least one on-treatment measurement for A1C.

Reporting Groups

	Description
Sitagliptin (Phase A)	In Phase A (Treatment Day 1 up to Week 12), participants were administered 100 mg q.d. of sitagliptin or matching placebo.
Pioglitazone (Phase A)	In Phase A (Treatment Day 1 up to Week 12), participants in the Pioglitazone group were administered 15 mg q.d. of pioglitazone or matching placebo. At Week 6, participants were administered 30 mg q.d. pioglitazone.

Measured Values

	Sitagliptin (Phase A)	**Pioglitazone (Phase A)**
Number of Participants Analyzed [units: participants]	**231**	**240**
Change in Hemoglobin A1c (A1C) in Participants Treated With Sitagliptin or Pioglitazone at 12 Weeks [units: percentage of glycosylated hemoglobin] Least Squares Mean (95% Confidence Interval)	**-1.03 (-1.18 to -0.88)**	**-0.87 (-1.02 to -0.72)**

Statistical Analysis 1 for Change in Hemoglobin A1c (A1C) in Participants Treated With Sitagliptin or Pioglitazone at 12 Weeks

Groups [1]	All groups
Method [2]	ANCOVA
Difference in LS Means [3]	-0.16
95% Confidence Interval	-0.37 to 0.05

[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:

	For Least Squares Mean, the ANCOVA model included a term for treatment and the baseline value as a covariate.
[3]	Other relevant estimation information:
	No text entered.

3. Secondary: Change in 2-hour Postprandial Glucose (PMG) in the Sita/Met FDC or Pioglitazone Groups at 40 Weeks [Time Frame: Baseline and 40 weeks]

Measure Type	Secondary
Measure Title	Change in 2-hour Postprandial Glucose (PMG) in the Sita/Met FDC or Pioglitazone Groups at 40 Weeks
Measure Description	The change in PMG compared to baseline was measured using the Meal Tolerance Test (MTT) for the Sita/Met FDC and the pioglitazone groups at Week 40.
Time Frame	Baseline and 40 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.
All randomized participants who (1) took at least one dose of study medication; i.e., sitagliptin or pioglitazone 15/30 mg q.d. for the Weeks 0-12, and Sita/Met FDC or pioglitazone 45 mg q.d. for the Weeks 0-40 (Phase A and Phase B); and (2) had a baseline measurement and at least one on-treatment measurement for PMG.

Reporting Groups

	Description
Sita/Met FDC	In Phase A (Treatment Day 1 up to Week 12), participants were administered 100 mg once daily (q.d.) of sitagliptin and matching placebo to pioglitazone. In Phase B (Treatment Week 12 to Week 40), participants that continued were switched to the Sita/Met Fixed-Dose Combination (FDC) at a dose of 50/500 mg twice a day (b.i.d.), which was increased to 50/1000 mg b.i.d. over a period of 4 weeks.
Pioglitazone	In Phase A (Treatment Day 1 up to Week 12), participants in the pioglitazone group were administered 15 mg once daily (q.d.) of pioglitazone and matching placebo to sitagliptin. At Week 6, all participants were administered 30 mg q.d. pioglitazone. In Phase B (Treatment Week 12 to Week 40), participants that continued were administered 45 mg pioglitazone once daily (q.d.).

Measured Values

	Sita/Met FDC	**Pioglitazone**
Number of Participants Analyzed [units: participants]	**165**	**172**
Change in 2-hour Postprandial Glucose (PMG) in the Sita/Met FDC or Pioglitazone Groups at 40 Weeks [units: mg/dL] Least Squares Mean (95% Confidence Interval)	**-90.3 (-99.6 to -81.0)**	**-69.1 (-78.2 to -60.0)**

Statistical Analysis 1 for Change in 2-hour Postprandial Glucose (PMG) in the Sita/Met FDC or Pioglitazone Groups at 40 Weeks

Groups [1]	All groups

Method [2]	ANCOVA
P Value [3]	0.001

[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:
	For Least Squares Mean, the ANCOVA model included a term for treatment and the baseline value as a covariate.
[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. Secondary: Change in 2-hour Postprandial Glucose (PMG) in Participants Treated With Sitagliptin or Pioglitazone at 12 Weeks [Time Frame: Baseline to 12 weeks]

Measure Type	Secondary
Measure Title	Change in 2-hour Postprandial Glucose (PMG) in Participants Treated With Sitagliptin or Pioglitazone at 12 Weeks
Measure Description	The change in PMG compared to baseline was measured using the Meal Tolerance Test (MTT) for the participants treated with Sitagliptin or Pioglitazone at Week 12. Sitagliptin was the only intervention administered to the Sita/Met FDC group during this phase. To calculate Least Squares, the ANCOVA model included a term for treatment and the baseline value as a covariate.
Time Frame	Baseline to 12 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.
All randomized participants who (1) took at least one dose of study medication; i.e., sitagliptin or pioglitazone 15/30 mg q.d. for the Weeks 0-12; and (2) had a baseline measurement and at least one on-treatment measurement for PMG.

Reporting Groups

	Description
Sitagliptin (Phase A)	In Phase A (Treatment Day 1 up to Week 12), participants were administered 100 mg q.d. of sitagliptin or matching placebo.
Pioglitazone (Phase A)	In Phase A (Treatment Day 1 up to Week 12), participants in the Pioglitazone group were administered 15 mg q.d. of pioglitazone or matching placebo. At Week 6, participants were administered 30 mg q.d. pioglitazone.

Measured Values

	Sitagliptin (Phase A)	**Pioglitazone (Phase A)**
Number of Participants Analyzed [units: participants]	**202**	**210**
Change in 2-hour Postprandial Glucose (PMG) in Participants Treated With Sitagliptin or Pioglitazone at 12 Weeks [units: mg/dL] Least Squares Mean (95% Confidence Interval)	**-52.8 (-62.4 to -43.3)**	**-50.1 (-59.4 to -40.7)**

No statistical analysis provided for Change in 2-hour Postprandial Glucose (PMG) in Participants Treated With Sitagliptin or Pioglitazone at 12 Weeks

5. Secondary: Change in Fasting Plasma Glucose (FPG) in the Sita/Met FDC or Pioglitazone Groups at 40 Weeks [Time Frame: Baseline and 40 weeks]

Measure Type	Secondary
Measure Title	Change in Fasting Plasma Glucose (FPG) in the Sita/Met FDC or Pioglitazone Groups at 40 Weeks
Measure Description	The change in FPG compared to baseline was measured for the Sita/Met FDC and the pioglitazone groups at Week 40.
Time Frame	Baseline and 40 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.
All randomized participants who (1) took at least one dose of study medication; i.e., sitagliptin or pioglitazone 15/30 mg q.d. for the Weeks 0-12, and Sita/Met FDC or pioglitazone 45 mg q.d. for the Weeks 0-40 (Phase A and Phase B); and (2) had a baseline measurement and at least one on-treatment measurement for FPG.

Reporting Groups

	Description
Sita/Met FDC	In Phase A (Treatment Day 1 up to Week 12), participants were administered 100 mg once daily (q.d.) of sitagliptin and matching placebo to pioglitazone. In Phase B (Treatment Week 12 to Week 40), participants that continued were switched to the Sita/Met Fixed-Dose Combination (FDC) at a dose of 50/500 mg twice a day (b.i.d.), which was increased to 50/1000 mg b.i.d. over a period of 4 weeks.
Pioglitazone	In Phase A (Treatment Day 1 up to Week 12), participants in the pioglitazone group were administered 15 mg once daily (q.d.) of pioglitazone and matching placebo to sitagliptin. At Week 6, all participants were administered 30 mg q.d. pioglitazone. In Phase B (Treatment Week 12 to Week 40), participants that continued were administered 45 mg pioglitazone once daily (q.d.).

Measured Values

	Sita/Met FDC	**Pioglitazone**
Number of Participants Analyzed [units: participants]	**219**	**226**
Change in Fasting Plasma Glucose (FPG) in the Sita/Met FDC or Pioglitazone Groups at 40 Weeks [units: mg/dL] Least Squares Mean (95% Confidence Interval)	**-45.8 (-51.1 to -40.5)**	**-37.6 (-42.8 to -32.4)**

Statistical Analysis 1 for Change in Fasting Plasma Glucose (FPG) in the Sita/Met FDC or Pioglitazone Groups at 40 Weeks

Groups [1]	All groups
Method [2]	ANCOVA

P Value [3]	0.030

[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:
	For Least Squares Mean, the ANCOVA model included a term for treatment and the baseline value as a covariate.
[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.

6. Secondary: Change in Fasting Plasma Glucose (FPG) in Participants Treated With Sitagliptin or Pioglitazone at 12 Weeks [Time Frame: Baseline to 12 weeks]

Measure Type	Secondary
Measure Title	Change in Fasting Plasma Glucose (FPG) in Participants Treated With Sitagliptin or Pioglitazone at 12 Weeks
Measure Description	The change in FPG compared to baseline was measured for the participants treated with sitagliptin or pioglitazone at Week 12. Sitagliptin was the only intervention administered to the Sita/Met FDC group during this phase. To calculate Least Squares, the ANCOVA model included a term for treatment and the baseline value as a covariate.
Time Frame	Baseline to 12 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.
All randomized participants who (1) took at least one dose of study medication; i.e., sitagliptin or pioglitazone 15/30 mg q.d. for the Weeks 0-12; and (2) had a baseline measurement and at least one on-treatment measurement for FPG.

Reporting Groups

	Description
Sitagliptin (Phase A)	In Phase A (Treatment Day 1 up to Week 12), participants were administered 100 mg q.d. of sitagliptin or matching placebo.
Pioglitazone (Phase A)	In Phase A (Treatment Day 1 up to Week 12), participants in the Pioglitazone group were administered 15 mg q.d. of pioglitazone or matching placebo. At Week 6, participants were administered 30 mg q.d. pioglitazone.

Measured Values

	Sitagliptin (Phase A)	**Pioglitazone (Phase A)**
Number of Participants Analyzed [units: participants]	**235**	**245**
Change in Fasting Plasma Glucose (FPG) in Participants Treated With Sitagliptin or Pioglitazone at 12 Weeks [units: mg/dL] Least Squares Mean (95% Confidence Interval)	**-26.6 (-31.7 to -21.5)**	**-28.0 (-33.0 to -23.0)**

No statistical analysis provided for Change in Fasting Plasma Glucose (FPG) in Participants Treated With Sitagliptin or Pioglitazone at 12 Weeks

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	No text entered.
Additional Description	Participants that received at least one dose of study medication, which was sitagliptin or pioglitazone 15/30 mg q.d. for the Weeks 0-12 and Sita/Met FDC or pioglitazone 45 mg q.d. for the Weeks 0-40 were analyzed. The analyses for Week 0-40 did not include participants who discontinued from the study during Weeks 0-12.

Reporting Groups

	Description
Sitagliptin (Weeks 0-12)	In Phase A (Treatment Day 1 up to Week 12), participants were administered 100 mg q.d. of sitagliptin or matching placebo to pioglitazone.
Pioglitazone (Weeks 0-12)	In Phase A (Treatment Day 1 up to Week 12), randomized participants in the pioglitazone group were administered 15 mg q.d. of pioglitazone or matching placebo to sitagliptin. At Week 6, all participants were up-titrated to 30 mg q.d. pioglitazone.
Sita/Met FDC (Weeks 0-40)	In Phase A (Treatment Day 1 up to Week 12), participants were administered 100 mg q.d. of sitagliptin or matching placebo to pioglitazone. In Phase B (Treatment Week 12-Week 40), participants were switched to the Sita/Met Fixed-Dose Combination (FDC) at a dose of 50/500 mg b.i.d., which was increased to 50/1000 mg b.i.d. over a period of 4 weeks.
Pioglitazone (Weeks 0-40)	In Phase A (Treatment Day 1 up to Week 12), randomized participants in the pioglitazone group were administered 15 mg q.d. of pioglitazone or matching placebo to sitagliptin. At Week 6, participants were up-titrated to 30 mg q.d. In Phase B (Treatment Week 12 -Week 40), participants were administered 45 mg q.d.

Serious Adverse Events

	Sitagliptin (Weeks 0-12)	Pioglitazone (Weeks 0-12)	Sita/Met FDC (Weeks 0-40)	Pioglitazone (Weeks 0-40)
Total, serious adverse events				
# participants affected / at risk	**3/244 (1.23%)**	**1/248 (0.40%)**	**8/222 (3.60%)**	**3/230 (1.30%)**
Cardiac disorders				
Angina pectoris † 1				
# participants affected / at risk	**0/244 (0.00%)**	**0/248 (0.00%)**	**1/222 (0.45%)**	**0/230 (0.00%)**
# events	**0**	**0**	**1**	**0**
Atrial fibrillation † 1				
# participants affected / at risk	**0/244 (0.00%)**	**0/248 (0.00%)**	**0/222 (0.00%)**	**1/230 (0.43%)**
# events	**0**	**0**	**0**	**1**
Myocardial infarction † 1				
# participants affected / at risk	**0/244 (0.00%)**	**0/248 (0.00%)**	**1/222 (0.45%)**	**0/230 (0.00%)**
# events	**0**	**0**	**1**	**0**
Gastrointestinal disorders				
Inguinal hernia † 1				
# participants affected / at risk	**0/244 (0.00%)**	**0/248 (0.00%)**	**1/222 (0.45%)**	**0/230 (0.00%)**
# events	**0**	**0**	**1**	**0**
General disorders				

Sudden cardiac death † 1				
# participants affected / at risk	**0/244 (0.00%)**	**0/248 (0.00%)**	**1/222 (0.45%)**	**0/230 (0.00%)**
# events	**0**	**0**	**1**	**0**
Infections and infestations				
Gastroenteritis † 1				
# participants affected / at risk	**1/244 (0.41%)**	**0/248 (0.00%)**	**1/222 (0.45%)**	**0/230 (0.00%)**
# events	**1**	**0**	**1**	**0**
Infection parasitic † 1				
# participants affected / at risk	**1/244 (0.41%)**	**0/248 (0.00%)**	**0/222 (0.00%)**	**0/230 (0.00%)**
# events	**1**	**0**	**0**	**0**
Injury, poisoning and procedural complications				
Eye injury † 1				
# participants affected / at risk	**0/244 (0.00%)**	**0/248 (0.00%)**	**1/222 (0.45%)**	**0/230 (0.00%)**
# events	**0**	**0**	**1**	**0**
Musculoskeletal and connective tissue disorders				
Intervertebral disc protrusion † 1				
# participants affected / at risk	**0/244 (0.00%)**	**0/248 (0.00%)**	**1/222 (0.45%)**	**0/230 (0.00%)**
# events	**0**	**0**	**1**	**0**
Nervous system disorders				
Syncope † 1				
# participants affected / at risk	**0/244 (0.00%)**	**0/248 (0.00%)**	**1/222 (0.45%)**	**0/230 (0.00%)**
# events	**0**	**0**	**1**	**0**
Pregnancy, puerperium and perinatal conditions				
Abortion spontaneous † 1				
# participants affected / at risk	**0/244 (0.00%)**	**0/248 (0.00%)**	**0/222 (0.00%)**	**1/230 (0.43%)**
# events	**0**	**0**	**0**	**1**
Reproductive system and breast disorders				
Endometrial hyperplasia † 1				
# participants affected / at risk	**0/244 (0.00%)**	**1/248 (0.40%)**	**0/222 (0.00%)**	**1/230 (0.43%)**
# events	**0**	**1**	**0**	**1**
Prostatitis † 1				
# participants affected / at risk	**0/244 (0.00%)**	**0/248 (0.00%)**	**1/222 (0.45%)**	**0/230 (0.00%)**
# events	**0**	**0**	**1**	**0**
Vascular disorders				
Arterial thrombosis limb † 1				
# participants affected / at risk	**1/244 (0.41%)**	**0/248 (0.00%)**	**0/222 (0.00%)**	**0/230 (0.00%)**
# events	**1**	**0**	**0**	**0**

† Events were collected by systematic assessment

1 Term from vocabulary, MedDRA 12.1

Other Adverse Events

Hide Other Adverse Events

Time Frame	No text entered.
Additional Description	Participants that received at least one dose of study medication, which was sitagliptin or pioglitazone 15/30 mg q.d. for the Weeks 0-12 and Sita/Met FDC or pioglitazone 45 mg q.d. for the Weeks 0-40 were analyzed. The analyses for Week 0-40 did not include participants who discontinued from the study during Weeks 0-12.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Sitagliptin (Weeks 0-12)	In Phase A (Treatment Day 1 up to Week 12), participants were administered 100 mg q.d. of sitagliptin or matching placebo to pioglitazone.
Pioglitazone (Weeks 0-12)	In Phase A (Treatment Day 1 up to Week 12), randomized participants in the pioglitazone group were administered 15 mg q.d. of pioglitazone or matching placebo to sitagliptin. At Week 6, all participants were up-titrated to 30 mg q.d. pioglitazone.
Sita/Met FDC (Weeks 0-40)	In Phase A (Treatment Day 1 up to Week 12), participants were administered 100 mg q.d. of sitagliptin or matching placebo to pioglitazone. In Phase B (Treatment Week 12-Week 40), participants were switched to the Sita/Met Fixed-Dose Combination (FDC) at a dose of 50/500 mg b.i.d., which was increased to 50/1000 mg b.i.d. over a period of 4 weeks.
Pioglitazone (Weeks 0-40)	In Phase A (Treatment Day 1 up to Week 12), randomized participants in the pioglitazone group were administered 15 mg q.d. of pioglitazone or matching placebo to sitagliptin. At Week 6, participants were up-titrated to 30 mg q.d. In Phase B (Treatment Week 12 -Week 40), participants were administered 45 mg q.d.

Other Adverse Events

	Sitagliptin (Weeks 0-12)	Pioglitazone (Weeks 0-12)	Sita/Met FDC (Weeks 0-40)	Pioglitazone (Weeks 0-40)
Total, other (not including serious) adverse events				
# participants affected / at risk	**7/244 (2.87%)**	**15/248 (6.05%)**	**20/222 (9.01%)**	**33/230 (14.35%)**
General disorders				
Oedema peripheral † 1				
# participants affected / at risk	**0/244 (0.00%)**	**7/248 (2.82%)**	**2/222 (0.90%)**	**13/230 (5.65%)**
# events	**0**	**7**	**2**	**15**
Infections and infestations				
Nasopharyngitis † 1				
# participants affected / at risk	**4/244 (1.64%)**	**6/248 (2.42%)**	**12/222 (5.41%)**	**12/230 (5.22%)**
# events	**4**	**6**	**14**	**17**
Nervous system disorders				
Headache † 1				
# participants affected / at risk	**4/244 (1.64%)**	**4/248 (1.61%)**	**9/222 (4.05%)**	**12/230 (5.22%)**
# events	**4**	**4**	**13**	**16**

† Events were collected by systematic assessment

1 Term from vocabulary, MedDRA 12.1

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:** The disclosure restriction on the PI is that an investigator and/or his/her colleagues may publish the results for their study site independently subsequent to the multicenter publication, or 24 months after completion of the study, whichever comes first. 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 from the time submitted to the sponsor for review.

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Publications of Results:

Pérez-Monteverde A, Seck T, Xu L, Lee MA, Sisk CM, Williams-Herman DE, Engel SS, Kaufman KD, Goldstein BJ. Efficacy and safety of sitagliptin and the fixed-dose combination of sitagliptin and metformin vs. pioglitazone in drug-naïve patients with type 2 diabetes. Int J Clin Pract. 2011 Sep;65(9):930-8. doi: 10.1111/j.1742-1241.2011.02749.x.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00541450 History of Changes
Other Study ID Numbers:	0431-068 2007_501
Study First Received:	October 5, 2007
Results First Received:	January 13, 2011
Last Updated:	May 4, 2015
Health Authority:	United States: Food and Drug Administration

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