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MK0431 and Pioglitazone Co-Administration Factorial Study in Patients With Type 2 Diabetes Mellitus (0431-102 AM2)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

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

ClinicalTrials.gov Identifier:
NCT00722371

First received: July 22, 2008
Last updated: March 23, 2015
Last verified: March 2015
History of Changes

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Purpose

A study to evaluate the efficacy and safety of sitagliptin and pioglitazone co-administration in comparison with sitagliptin and pioglitazone monotherapy in patients with type 2 diabetes.

Condition	Intervention	Phase
Type 2 Diabetes Mellitus	Drug: Sitagliptin phosphate Drug: Pioglitazone hydrochloride Drug: Matching placebo to sitagliptin Drug: Matching placebo to pioglitazone Drug: 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, Randomized, Double-Blind Study of the Co-Administration of Sitagliptin and Pioglitazone in Patients With Type 2 Diabetes Mellitus Who Have Inadequate Glycemic Control

Resource links provided by NLM:

MedlinePlus related topics: Diabetes Type 2

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

U.S. FDA Resources

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

Primary Outcome Measures:

- Change From Baseline in Hemoglobin A1C (A1C) at Week 24 [Time Frame: Baseline and Week 24] [Designated as safety issue: No]

  A1C represents the percentage of glycosylated hemoglobin.

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

  A1C represents the percentage of glycosylated hemoglobin.

Secondary Outcome Measures:

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

  PMG was measured using the Meal Tolerance Test (MTT).

- Change From Baseline in FPG at Week 54 [Time Frame: Baseline and Week 54] [Designated as safety issue: No]
- Change From Baseline in 2-Hour PMG at Week 54 [Time Frame: Baseline and Week 54] [Designated as safety issue: No]

  PMG was measured using the Meal Tolerance Test (MTT).

Enrollment:	1615
Study Start Date:	September 2008
Study Completion Date:	March 2011
Primary Completion Date:	October 2010 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: Sitagliptin 100 mg	Drug: Sitagliptin phosphate Sitagliptin 100 mg tablet (blinded) orally once daily for 54 weeks. Other Names: • Januvia • Tesavel • Xelevia • Ristaben Drug: Matching placebo to pioglitazone Matching placebo to pioglitazone tablets or capsules orally once daily for 54 weeks. Drug: Metformin Metformin 500 mg (open-label) was to be initiated as rescue therapy to participants not meeting specific glycemic goals. The dose of metformin may have been uptitrated and adjusted, at the discretion of the investigator, up to the maximum approved dose in the country of origin.
Experimental: Pioglitazone 15 mg	Drug: Pioglitazone hydrochloride Pioglitazone 15 mg, 30 mg, or 45 mg tablets or capsules (blinded) orally once daily for 54 weeks. Participants randomized to receive pioglitazone 45 mg as monotherapy or in combination with sitagliptin were to start on pioglitazone 30 mg at Week 1 and undergo uptitration to pioglitazone 45 mg at Week 4. Other Name: Actos Drug: Matching placebo to sitagliptin Matching placebo to sitagliptin orally once daily for 54 weeks. Drug: Metformin Metformin 500 mg (open-label) was to be initiated as rescue therapy to participants not meeting specific glycemic goals. The dose of metformin may have been uptitrated and adjusted, at the discretion of the investigator, up to the maximum approved dose in the country of origin.
Experimental: Pioglitazone 30	Drug: Pioglitazone hydrochloride Pioglitazone 15 mg, 30 mg, or 45 mg tablets or capsules (blinded) orally once daily for 54 weeks. Participants randomized

mg	to receive pioglitazone 45 mg as monotherapy or in combination with sitagliptin were to start on pioglitazone 30 mg at Week 1 and undergo uptitration to pioglitazone 45 mg at Week 4. Other Name: Actos Drug: Matching placebo to sitagliptin Matching placebo to sitagliptin orally once daily for 54 weeks. Drug: Metformin Metformin 500 mg (open-label) was to be initiated as rescue therapy to participants not meeting specific glycemic goals. The dose of metformin may have been uptitrated and adjusted, at the discretion of the investigator, up to the maximum approved dose in the country of origin.
Experimental: Pioglitazone 45 mg	Drug: Pioglitazone hydrochloride Pioglitazone 15 mg, 30 mg, or 45 mg tablets or capsules (blinded) orally once daily for 54 weeks. Participants randomized to receive pioglitazone 45 mg as monotherapy or in combination with sitagliptin were to start on pioglitazone 30 mg at Week 1 and undergo uptitration to pioglitazone 45 mg at Week 4. Other Name: Actos Drug: Matching placebo to sitagliptin Matching placebo to sitagliptin orally once daily for 54 weeks. Drug: Metformin Metformin 500 mg (open-label) was to be initiated as rescue therapy to participants not meeting specific glycemic goals. The dose of metformin may have been uptitrated and adjusted, at the discretion of the investigator, up to the maximum approved dose in the country of origin.
Experimental: Sitagliptin 100 mg/ Pioglitazone 15 mg	Drug: Sitagliptin phosphate Sitagliptin 100 mg tablet (blinded) orally once daily for 54 weeks. Other Names: • Januvia • Tesavel • Xelevia • Ristaben Drug: Pioglitazone hydrochloride Pioglitazone 15 mg, 30 mg, or 45 mg tablets or capsules (blinded) orally once daily for 54 weeks. Participants randomized to receive pioglitazone 45 mg as monotherapy or in combination with sitagliptin were to start on pioglitazone 30 mg at Week 1 and undergo uptitration to pioglitazone 45 mg at Week 4. Other Name: Actos Drug: Metformin Metformin 500 mg (open-label) was to be initiated as rescue therapy to participants not meeting specific glycemic goals. The dose of metformin may have been uptitrated and adjusted, at the discretion of the investigator, up to the maximum approved dose in the country of origin.
Experimental: Sitagliptin 100 mg/ Pioglitazone 30 mg	Drug: Sitagliptin phosphate Sitagliptin 100 mg tablet (blinded) orally once daily for 54 weeks. Other Names: • Januvia • Tesavel • Xelevia • Ristaben Drug: Pioglitazone hydrochloride Pioglitazone 15 mg, 30 mg, or 45 mg tablets or capsules (blinded) orally once daily for 54 weeks. Participants randomized to receive pioglitazone 45 mg as monotherapy or in combination with sitagliptin were to start on pioglitazone 30 mg at Week 1 and undergo uptitration to pioglitazone 45 mg at Week 4. Other Name: Actos Drug: Metformin Metformin 500 mg (open-label) was to be initiated as rescue therapy to participants not meeting specific glycemic goals. The dose of metformin may have been uptitrated and adjusted, at the discretion of the investigator, up to the maximum approved dose in the country of origin.
Experimental:	Drug: Sitagliptin phosphate

Sitagliptin 100 mg/ Pioglitazone 45 mg	Sitagliptin 100 mg tablet (blinded) orally once daily for 54 weeks. Other Names: • Januvia • Tesavel • Xelevia • Ristaben Drug: Pioglitazone hydrochloride Pioglitazone 15 mg, 30 mg, or 45 mg tablets or capsules (blinded) orally once daily for 54 weeks. Participants randomized to receive pioglitazone 45 mg as monotherapy or in combination with sitagliptin were to start on pioglitazone 30 mg at Week 1 and undergo uptitration to pioglitazone 45 mg at Week 4. Other Name: Actos Drug: Metformin Metformin 500 mg (open-label) was to be initiated as rescue therapy to participants not meeting specific glycemic goals. The dose of metformin may have been uptitrated and adjusted, at the discretion of the investigator, up to the maximum approved dose in the country of origin.

Eligibility

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

Criteria

Inclusion Criteria:

- Patient is highly unlikely to conceive
- Patient meets one of the 3 categories is naïve to all antihyperglycemic agent (AHA) therapies, or is non-naïve based upon the patient's current diet, medical regimen and screening A1c patient is currently not on AHA with a screening A1c >=7.5 % and =<11.0 % patient is currently on either metformin pr sulfonylurea monotherapy with a screening A1c >=7.0 % and =<9.0 %

Exclusion Criteria

- Patient has a history of type 1 diabetes mellitus or history of ketoacidosis or has C=peptide value of =<0.8 ng/mL
- Patient has previously been treated with insulin, thiazolidinedione (TZD) (rosiglitazone or pioglitazone), any Dipeptidyl peptidase-4 (DPP-4) inhibitor (sitagliptin, vildagliptin, or alogliptin), exenatide or has previously been in a clinical study with any DPP-4 inhibitor or incretin mimetic
- Patient is on a weight loss program and is not in the maintenance phase or has started a weight loss medication (e.g. orlistat or sibutramine) within the prior 8 weeks
- Patient has undergone surgery within the prior 30 days or has major surgery planned during the study
- Patient has a medical history of active liver disease including chronic active hepatitis B or C or symptomatic gallbladder disease including primary biliary cirrhosis
- Patient has received treatment with an investigational product within 12 weeks prior to Visit 1

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.

No Contacts or Locations Provided

More Information

Publications:

Henry RR, Staels B, Fonseca VA, Chou MZ, Teng R, Golm GT, Langdon RB, Kaufman KD, Steinberg H, Goldstein BJ. Efficacy and safety of initial combination treatment with sitagliptin and pioglitazone--a factorial study. Diabetes Obes Metab. 2014 Mar;16(3):223-30. doi: 10.1111/dom.12194. Epub 2013 Aug 29.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00722371 History of Changes
Other Study ID Numbers:	0431-102 2008_522
Study First Received:	July 22, 2008
Results First Received:	September 9, 2011
Last Updated:	March 23, 2015
Health Authority:	United States: Food and Drug Administration

Additional relevant MeSH terms:

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

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MK0431 and Pioglitazone Co-Administration Factorial Study in Patients With Type 2 Diabetes Mellitus (0431-102 AM2)

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First received: July 22, 2008
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History of Changes

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Results First Received: September 9, 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: Sitagliptin phosphate Drug: Pioglitazone hydrochloride Drug: Matching placebo to sitagliptin Drug: Matching placebo to pioglitazone Drug: 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
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
Sitagliptin 100 mg	Sitagliptin 100 mg and matching placebo to pioglitazone once daily for 54 weeks.
Pioglitazone 15 mg	Pioglitazone 15 mg and matching placebo to sitagliptin once daily for 54 weeks.
Pioglitazone 30 mg	Pioglitazone 30 mg and matching placebo to sitagliptin once daily for 54 weeks.

Pioglitazone 45 mg	Pioglitazone 45 mg and matching placebo to sitagliptin once daily for 54 weeks.
Sitagliptin 100 mg/ Pioglitazone 15 mg	Sitagliptin 100 mg and pioglitazone 15 mg once daily for 54 weeks.
Sitagliptin 100 mg/ Pioglitazone 30 mg	Sitagliptin 100 mg and pioglitazone 30 mg once daily for 54 weeks.
Sitagliptin 100 mg/ Pioglitazone 45 mg	Sitagliptin 100 mg and pioglitazone 45 mg once daily for 54 weeks.

Participant Flow: Overall Study

	Sitagliptin 100 mg	Pioglitazone 15 mg	Pioglitazone 30 mg	Pioglitazone 45 mg	Sitagliptin 100 mg/ Pioglitazone 15 mg	Sitagliptin 100 mg/ Pioglitazone 30 mg	Sitagliptin 100 mg/ Pioglitazone 45 mg
STARTED	231	230	233	230	230	231	230
COMPLETED	175	158	168	167	182	178	179
NOT COMPLETED	56	72	65	63	48	53	51
Adverse Event	6	13	9	10	6	8	4
Contraindication	0	0	1	0	0	0	0
Creatinine / Creatinine clearance	2	1	2	3	2	1	1
Excluded medication	0	1	1	0	0	0	1
Hyperglycemia	2	6	4	2	5	1	1
Hypoglycemia	1	0	0	0	0	0	0
Lack of Efficacy	4	6	6	6	2	3	0
Lost to Follow-up	11	14	21	13	8	16	13
Physician Decision	5	2	2	5	2	3	4
Pregnancy	1	1	0	0	0	1	0
Protocol Violation	6	1	0	1	4	2	1
Withdrawal by Subject	18	27	19	23	19	18	26

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	Sitagliptin 100 mg and matching placebo to pioglitazone once daily for 54 weeks.
Pioglitazone 15 mg	Pioglitazone 15 mg and matching placebo to sitagliptin once daily for 54 weeks.
Pioglitazone 30 mg	Pioglitazone 30 mg and matching placebo to sitagliptin once daily for 54 weeks.
Pioglitazone 45 mg	Pioglitazone 45 mg and matching placebo to sitagliptin once daily for 54 weeks.

Sitagliptin 100 mg/ Pioglitazone 15 mg	Sitagliptin 100 mg and pioglitazone 15 mg once daily for 54 weeks.
Sitagliptin 100 mg/ Pioglitazone 30 mg	Sitagliptin 100 mg and pioglitazone 30 mg once daily for 54 weeks.
Sitagliptin 100 mg/ Pioglitazone 45 mg	Sitagliptin 100 mg and pioglitazone 45 mg once daily for 54 weeks.
Total	Total of all reporting groups

Baseline Measures

	Sitagliptin 100 mg	Pioglitazone 15 mg	Pioglitazone 30 mg	Pioglitazone 45 mg	Sitagliptin 100 mg/ Pioglitazone 15 mg	Sitagliptin 100 mg/ Pioglitazone 30 mg	Sitagliptin 100 mg/ Pioglitazone 45 mg	Total
Number of Participants [units: participants]	**231**	**230**	**233**	**230**	**230**	**231**	**230**	**1615**
Age, Customized [units: Participants]								
<=20 years	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**
21 to 30 years	**5**	**6**	**2**	**5**	**5**	**8**	**4**	**35**
31 to 40 years	**37**	**39**	**33**	**20**	**17**	**34**	**15**	**195**
41 to 50 years	**64**	**73**	**60**	**70**	**73**	**60**	**68**	**468**
51 to 60 years	**83**	**67**	**88**	**76**	**80**	**75**	**87**	**556**
61 to 70 years	**31**	**34**	**45**	**53**	**44**	**49**	**51**	**307**
>70 years	**11**	**11**	**5**	**6**	**11**	**5**	**5**	**54**
Gender [units: participants]								
Female	**95**	**82**	**106**	**117**	**112**	**96**	**95**	**703**
Male	**136**	**148**	**127**	**113**	**118**	**135**	**135**	**912**

Outcome Measures

Hide All Outcome Measures

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

Measure Type	Primary
Measure Title	Change From Baseline in Hemoglobin A1C (A1C) at Week 24
Measure Description	A1C represents the percentage of glycosylated hemoglobin.
Time Frame	Baseline and Week 24
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.

Full Analysis Set with last observation carried forward (LOCF). Reasons for exclusion included no baseline data and/or no post-baseline data.

Reporting Groups

	Description
Sitagliptin 100 mg	Sitagliptin 100 mg and matching placebo to pioglitazone once daily for 54 weeks.
Pioglitazone 15 mg	Pioglitazone 15 mg and matching placebo to sitagliptin once daily for 54 weeks.
Pioglitazone 30 mg	Pioglitazone 30 mg and matching placebo to sitagliptin once daily for 54 weeks.
Pioglitazone 45 mg	Pioglitazone 45 mg and matching placebo to sitagliptin once daily for 54 weeks.
Sitagliptin 100 mg/ Pioglitazone 15 mg	Sitagliptin 100 mg and pioglitazone 15 mg once daily for 54 weeks.
Sitagliptin 100 mg/ Pioglitazone 30 mg	Sitagliptin 100 mg and pioglitazone 30 mg once daily for 54 weeks.
Sitagliptin 100 mg/ Pioglitazone 45 mg	Sitagliptin 100 mg and pioglitazone 45 mg once daily for 54 weeks.

Measured Values

	Sitagliptin 100 mg	Pioglitazone 15 mg	Pioglitazone 30 mg	Pioglitazone 45 mg	Sitagliptin 100 mg/ Pioglitazone 15 mg	Sitagliptin 100 mg/ Pioglitazone 30 mg	Sitagliptin 100 mg/ Pioglitazone 45 mg
Number of Participants Analyzed [units: participants]	**172**	**163**	**181**	**171**	**179**	**173**	**188**
Change From Baseline in Hemoglobin A1C (A1C) at Week 24 [units: Percentage of glycosylated hemoglobin] Least Squares Mean (95% Confidence Interval)	**-1.09 (-1.29 to -0.89)**	**-0.88 (-1.09 to -0.68)**	**-1.21 (-1.41 to -1.02)**	**-1.20 (-1.40 to -1.00)**	**-1.53 (-1.73 to -1.34)**	**-1.63 (-1.82 to -1.43)**	**-1.81 (-2.00 to -1.62)**

No statistical analysis provided for Change From Baseline in Hemoglobin A1C (A1C) at Week 24

2. Primary: Change From Baseline in A1C at Week 54 [Time Frame: Baseline and Week 54]

Measure Type	Primary
Measure Title	Change From Baseline in A1C at Week 54
Measure Description	A1C represents the percentage of glycosylated hemoglobin.
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.

Full Analysis Set with LOCF. Reasons for exclusion included no baseline data and/or no post-baseline data.

Reporting Groups

	Description
Sitagliptin 100 mg	Sitagliptin 100 mg and matching placebo to pioglitazone once daily for 54 weeks.
Pioglitazone 15 mg	Pioglitazone 15 mg and matching placebo to sitagliptin once daily for 54 weeks.
Pioglitazone 30 mg	Pioglitazone 30 mg and matching placebo to sitagliptin once daily for 54 weeks.
Pioglitazone 45 mg	Pioglitazone 45 mg and matching placebo to sitagliptin once daily for 54 weeks.
Sitagliptin 100 mg/ Pioglitazone 15 mg	Sitagliptin 100 mg and pioglitazone 15 mg once daily for 54 weeks.
Sitagliptin 100 mg/ Pioglitazone 30 mg	Sitagliptin 100 mg and pioglitazone 30 mg once daily for 54 weeks.
Sitagliptin 100 mg/ Pioglitazone 45 mg	Sitagliptin 100 mg and pioglitazone 45 mg once daily for 54 weeks.

Measured Values

	Sitagliptin 100 mg	Pioglitazone 15 mg	Pioglitazone 30 mg	Pioglitazone 45 mg	Sitagliptin 100 mg/ Pioglitazone 15 mg	Sitagliptin 100 mg/ Pioglitazone 30 mg	Sitagliptin 100 mg/ Pioglitazone 45 mg
Number of Participants Analyzed [units: participants]	172	163	181	171	179	173	188
Change From Baseline in A1C at Week 54 [units: Percent of glycosylated hemoglobin] Least Squares Mean (95% Confidence Interval)	-0.93 (-1.15 to -0.72)	-0.74 (-0.96 to -0.53)	-1.16 (-1.37 to -0.95)	-1.23 (-1.45 to -1.02)	-1.45 (-1.65 to -1.24)	-1.49 (-1.71 to -1.28)	-1.78 (-1.99 to -1.58)

No statistical analysis provided for Change From Baseline in A1C at Week 54

3. Secondary: Change From Baseline in Fasting Plasma Glucose (FPG) at Week 24 [Time Frame: Baseline and Week 24]

Measure Type	Secondary
Measure Title	Change From Baseline in Fasting Plasma Glucose (FPG) at Week 24
Measure Description	No text entered.
Time Frame	Baseline and Week 24
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full Analysis Set with LOCF. Reasons for exclusion included no baseline data and/or no post-baseline data.

Reporting Groups

	Description
Sitagliptin 100 mg	Sitagliptin 100 mg and matching placebo to pioglitazone once daily for 54 weeks.
Pioglitazone 15 mg	Pioglitazone 15 mg and matching placebo to sitagliptin once daily for 54 weeks.
Pioglitazone 30 mg	Pioglitazone 30 mg and matching placebo to sitagliptin once daily for 54 weeks.
Pioglitazone 45 mg	Pioglitazone 45 mg and matching placebo to sitagliptin once daily for 54 weeks.
Sitagliptin 100 mg/ Pioglitazone 15 mg	Sitagliptin 100 mg and pioglitazone 15 mg once daily for 54 weeks.
Sitagliptin 100 mg/ Pioglitazone 30 mg	Sitagliptin 100 mg and pioglitazone 30 mg once daily for 54 weeks.
Sitagliptin 100 mg/ Pioglitazone 45 mg	Sitagliptin 100 mg and pioglitazone 45 mg once daily for 54 weeks.

Measured Values

	Sitagliptin 100 mg	Pioglitazone 15 mg	Pioglitazone 30 mg	Pioglitazone 45 mg	Sitagliptin 100 mg/ Pioglitazone 15 mg	Sitagliptin 100 mg/ Pioglitazone 30 mg	Sitagliptin 100 mg/ Pioglitazone 45 mg
Number of Participants Analyzed [units: participants]	179	176	185	181	189	181	193
Change From Baseline in Fasting Plasma Glucose (FPG) at Week 24 [units: mg/dL] Least Squares Mean (95% Confidence Interval)	-24.3 (-32.0 to -16.5)	-19.5 (-27.2 to -11.7)	-29.9 (-37.6 to -22.3)	-37.4 (-45.1 to -29.7)	-41.0 (-48.5 to -33.5)	-46.9 (-54.6 to -39.3)	-52.0 (-59.6 to -44.5)

No statistical analysis provided for Change From Baseline in Fasting Plasma Glucose (FPG) at Week 24

4. Secondary: Change From Baseline in 2-Hour Post-meal Glucose (PMG) at Week 24 [Time Frame: Baseline and Week 24]

Measure Type	Secondary
Measure Title	Change From Baseline in 2-Hour Post-meal Glucose (PMG) at Week 24
Measure Description	PMG was measured using the Meal Tolerance Test (MTT).
Time Frame	Baseline and Week 24
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full Analysis Set with LOCF. Reasons for exclusion included no baseline data and/or no post-baseline data.

Reporting Groups

	Description
Sitagliptin 100 mg	Sitagliptin 100 mg and matching placebo to pioglitazone once daily for 54 weeks.
Pioglitazone 15 mg	Pioglitazone 15 mg and matching placebo to sitagliptin once daily for 54 weeks.
Pioglitazone 30 mg	Pioglitazone 30 mg and matching placebo to sitagliptin once daily for 54 weeks.
Pioglitazone 45 mg	Pioglitazone 45 mg and matching placebo to sitagliptin once daily for 54 weeks.
Sitagliptin 100 mg/ Pioglitazone 15 mg	Sitagliptin 100 mg and pioglitazone 15 mg once daily for 54 weeks.
Sitagliptin 100 mg/ Pioglitazone 30 mg	Sitagliptin 100 mg and pioglitazone 30 mg once daily for 54 weeks.
Sitagliptin 100 mg/ Pioglitazone 45 mg	Sitagliptin 100 mg and pioglitazone 45 mg once daily for 54 weeks.

Measured Values

	Sitagliptin 100 mg	**Pioglitazone 15 mg**	**Pioglitazone 30 mg**	**Pioglitazone 45 mg**	**Sitagliptin 100 mg/ Pioglitazone 15 mg**	**Sitagliptin 100 mg/ Pioglitazone 30 mg**	**Sitagliptin 100 mg/ Pioglitazone 45 mg**
Number of Participants Analyzed [units: participants]	**141**	**128**	**158**	**136**	**149**	**143**	**154**
Change From Baseline in 2-Hour Post-meal Glucose (PMG) at Week 24 [units: mg/dL] Least Squares Mean (95% Confidence Interval)	**-51.1 (-64.0 to -38.2)**	**-30.6 (-44.0 to -17.3)**	**-52.5 (-64.9 to -40.2)**	**-66.6 (-79.8 to -53.5)**	**-69.2 (-81.7 to -56.7)**	**-85.5 (-98.4 to -72.6)**	**-93.8 (-106.4 to -81.2)**

No statistical analysis provided for Change From Baseline in 2-Hour Post-meal Glucose (PMG) at Week 24

5. Secondary: Change From Baseline in FPG at Week 54 [Time Frame: Baseline and Week 54]

Measure Type	Secondary
Measure Title	Change From Baseline in FPG at Week 54
Measure Description	No text entered.
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.
Full Analysis Set with LOCF. Reasons for exclusion included no baseline data and/or no post-baseline data.

Reporting Groups

	Description
Sitagliptin 100 mg	Sitagliptin 100 mg and matching placebo to pioglitazone once daily for 54 weeks.
Pioglitazone 15 mg	Pioglitazone 15 mg and matching placebo to sitagliptin once daily for 54 weeks.
Pioglitazone 30 mg	Pioglitazone 30 mg and matching placebo to sitagliptin once daily for 54 weeks.
Pioglitazone 45 mg	Pioglitazone 45 mg and matching placebo to sitagliptin once daily for 54 weeks.
Sitagliptin 100 mg/ Pioglitazone 15 mg	Sitagliptin 100 mg and pioglitazone 15 mg once daily for 54 weeks.
Sitagliptin 100 mg/ Pioglitazone 30 mg	Sitagliptin 100 mg and pioglitazone 30 mg once daily for 54 weeks.
Sitagliptin 100 mg/ Pioglitazone 45 mg	Sitagliptin 100 mg and pioglitazone 45 mg once daily for 54 weeks.

Measured Values

	Sitagliptin 100 mg	**Pioglitazone 15 mg**	**Pioglitazone 30 mg**	**Pioglitazone 45 mg**	**Sitagliptin 100 mg/ Pioglitazone 15 mg**	**Sitagliptin 100 mg/ Pioglitazone 30 mg**	**Sitagliptin 100 mg/ Pioglitazone 45 mg**
Number of Participants Analyzed [units: participants]	**179**	**176**	**185**	**181**	**189**	**181**	**193**
Change From Baseline in FPG at Week 54 [units: mg/dL] Least Squares Mean (95% Confidence Interval)	**-13.1 (-21.6 to -4.5)**	**-10.5 (-19.0 to -2.0)**	**-24.0 (-32.4 to -15.5)**	**-33.3 (-41.8 to -24.8)**	**-33.9 (-42.2 to -25.7)**	**-37.1 (-45.5 to -28.6)**	**-47.8 (-56.1 to -39.5)**

No statistical analysis provided for Change From Baseline in FPG at Week 54

6. Secondary: Change From Baseline in 2-Hour PMG at Week 54 [Time Frame: Baseline and Week 54]

Measure Type	Secondary
Measure Title	Change From Baseline in 2-Hour PMG at Week 54
Measure Description	PMG was measured using the Meal Tolerance Test (MTT).
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.
Full Analysis Set with LOCF. Reasons for exclusion included no baseline data and/or no post-baseline data.

Reporting Groups

	Description
Sitagliptin 100 mg	Sitagliptin 100 mg and matching placebo to pioglitazone once daily for 54 weeks.
Pioglitazone 15 mg	Pioglitazone 15 mg and matching placebo to sitagliptin once daily for 54 weeks.
Pioglitazone 30 mg	Pioglitazone 30 mg and matching placebo to sitagliptin once daily for 54 weeks.
Pioglitazone 45 mg	Pioglitazone 45 mg and matching placebo to sitagliptin once daily for 54 weeks.
Sitagliptin 100 mg/ Pioglitazone 15 mg	Sitagliptin 100 mg and pioglitazone 15 mg once daily for 54 weeks.

Sitagliptin 100 mg/ Pioglitazone 30 mg	Sitagliptin 100 mg and pioglitazone 30 mg once daily for 54 weeks.
Sitagliptin 100 mg/ Pioglitazone 45 mg	Sitagliptin 100 mg and pioglitazone 45 mg once daily for 54 weeks.

Measured Values

	Sitagliptin 100 mg	Pioglitazone 15 mg	Pioglitazone 30 mg	Pioglitazone 45 mg	Sitagliptin 100 mg/ Pioglitazone 15 mg	Sitagliptin 100 mg/ Pioglitazone 30 mg	Sitagliptin 100 mg/ Pioglitazone 45 mg
Number of Participants Analyzed [units: participants]	**145**	**131**	**158**	**141**	**150**	**143**	**157**
Change From Baseline in 2-Hour PMG at Week 54 [units: mg/dL] Least Squares Mean (95% Confidence Interval)	**-37.0 (-50.2 to -23.7)**	**-26.7 (-40.5 to -13.0)**	**-46.8 (-59.6 to -34.1)**	**-58.2 (-71.6 to -44.7)**	**-64.7 (-77.6 to -51.8)**	**-69.7 (-83.1 to -56.4)**	**-88.2 (-101.2 to -75.3)**

No statistical analysis provided for Change From Baseline in 2-Hour PMG at Week 54

Serious Adverse Events

Hide Serious Adverse Events

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

Reporting Groups

	Description
Sitagliptin 100 mg	Sitagliptin 100 mg and matching placebo to pioglitazone once daily for 54 weeks.
Pioglitazone 15 mg	Pioglitazone 15 mg and matching placebo to sitagliptin once daily for 54 weeks.
Pioglitazone 30 mg	Pioglitazone 30 mg and matching placebo to sitagliptin once daily for 54 weeks.
Pioglitazone 45 mg	Pioglitazone 45 mg and matching placebo to sitagliptin once daily for 54 weeks.
Sitagliptin 100 mg/ Pioglitazone 15 mg	Sitagliptin 100 mg and pioglitazone 15 mg once daily for 54 weeks.
Sitagliptin 100 mg/ Pioglitazone 30 mg	Sitagliptin 100 mg and pioglitazone 30 mg once daily for 54 weeks.
Sitagliptin 100 mg/ Pioglitazone 45 mg	Sitagliptin 100 mg and pioglitazone 45 mg once daily for 54 weeks.

Serious Adverse Events

	Sitagliptin 100 mg	Pioglitazone 15 mg	Pioglitazone 30 mg	Pioglitazone 45 mg	Sitagliptin 100 mg/ Pioglitazone 15 mg	Sitagliptin 100 mg/ Pioglitazone 30 mg	Sitagliptin 100 mg/ Pioglitazone 45 mg
Total, serious adverse events							
# participants affected / at risk	**14/231 (6.06%)**	**10/230 (4.35%)**	**5/233 (2.15%)**	**11/230 (4.78%)**	**12/230 (5.22%)**	**15/231 (6.49%)**	**7/230 (3.04%)**
Cardiac disorders							
Angina unstable † 1							
# participants affected / at risk	**0/231 (0.00%)**	**0/230 (0.00%)**	**0/233 (0.00%)**	**0/230 (0.00%)**	**0/230 (0.00%)**	**1/231 (0.43%)**	**0/230 (0.00%)**
# events	**0**	**0**	**0**	**0**	**0**	**1**	**0**
Atrial fibrillation † 1							

# participants affected / at risk	0/231 (0.00%)	0/230 (0.00%)	0/233 (0.00%)	0/230 (0.00%)	0/230 (0.00%)	2/231 (0.87%)	0/230 (0.00%)
# events	0	0	0	0	0	2	0
Atrial flutter † 1							
# participants affected / at risk	0/231 (0.00%)	0/230 (0.00%)	0/233 (0.00%)	0/230 (0.00%)	0/230 (0.00%)	0/231 (0.00%)	1/230 (0.43%)
# events	0	0	0	0	0	0	1
Cardiac failure † 1							
# participants affected / at risk	0/231 (0.00%)	0/230 (0.00%)	0/233 (0.00%)	0/230 (0.00%)	0/230 (0.00%)	1/231 (0.43%)	0/230 (0.00%)
# events	0	0	0	0	0	1	0
Cardiac failure congestive † 1							
# participants affected / at risk	0/231 (0.00%)	0/230 (0.00%)	0/233 (0.00%)	0/230 (0.00%)	0/230 (0.00%)	0/231 (0.00%)	1/230 (0.43%)
# events	0	0	0	0	0	0	1
Coronary artery disease † 1							
# participants affected / at risk	2/231 (0.87%)	0/230 (0.00%)	0/233 (0.00%)	0/230 (0.00%)	1/230 (0.43%)	0/231 (0.00%)	0/230 (0.00%)
# events	2	0	0	0	1	0	0
Mitral valve disease † 1							
# participants affected / at risk	0/231 (0.00%)	0/230 (0.00%)	0/233 (0.00%)	0/230 (0.00%)	0/230 (0.00%)	0/231 (0.00%)	1/230 (0.43%)
# events	0	0	0	0	0	0	1
Myocardial infarction † 1							
# participants affected / at risk	0/231 (0.00%)	0/230 (0.00%)	0/233 (0.00%)	0/230 (0.00%)	1/230 (0.43%)	2/231 (0.87%)	0/230 (0.00%)
# events	0	0	0	0	1	2	0
Myocardial ischaemia † 1							
# participants affected / at risk	1/231 (0.43%)	0/230 (0.00%)	0/233 (0.00%)	0/230 (0.00%)	1/230 (0.43%)	0/231 (0.00%)	0/230 (0.00%)
# events	1	0	0	0	1	0	0
Supraventricular tachycardia † 1							
# participants affected / at risk	1/231 (0.43%)	0/230 (0.00%)	0/233 (0.00%)	0/230 (0.00%)	0/230 (0.00%)	0/231 (0.00%)	0/230 (0.00%)
# events	1	0	0	0	0	0	0
Eye disorders							
Optic ischaemic neuropathy † 1							
# participants affected / at risk	0/231 (0.00%)	0/230 (0.00%)	0/233 (0.00%)	1/230 (0.43%)	0/230 (0.00%)	0/231 (0.00%)	0/230 (0.00%)
# events	0	0	0	1	0	0	0
Gastrointestinal disorders							
Anal fissure † 1							
# participants affected / at risk	0/231 (0.00%)	0/230 (0.00%)	0/233 (0.00%)	0/230 (0.00%)	0/230 (0.00%)	0/231 (0.00%)	1/230 (0.43%)
# events	0	0	0	0	0	0	1
Gastrooesophageal reflux disease † 1							

# participants affected / at risk	0/231 (0.00%)	0/230 (0.00%)	0/233 (0.00%)	0/230 (0.00%)	1/230 (0.43%)	0/231 (0.00%)	0/230 (0.00%)
# events	0	0	0	0	1	0	0
Pancreatitis acute † 1							
# participants affected / at risk	0/231 (0.00%)	1/230 (0.43%)	0/233 (0.00%)	0/230 (0.00%)	0/230 (0.00%)	0/231 (0.00%)	0/230 (0.00%)
# events	0	1	0	0	0	0	0
Varices oesophageal † 1							
# participants affected / at risk	1/231 (0.43%)	0/230 (0.00%)	0/233 (0.00%)	0/230 (0.00%)	0/230 (0.00%)	0/231 (0.00%)	0/230 (0.00%)
# events	2	0	0	0	0	0	0
General disorders							
Non-cardiac chest pain † 1							
# participants affected / at risk	1/231 (0.43%)	0/230 (0.00%)	0/233 (0.00%)	0/230 (0.00%)	0/230 (0.00%)	1/231 (0.43%)	1/230 (0.43%)
# events	1	0	0	0	0	1	1
Hepatobiliary disorders							
Cholelithiasis † 1							
# participants affected / at risk	0/231 (0.00%)	0/230 (0.00%)	0/233 (0.00%)	0/230 (0.00%)	1/230 (0.43%)	0/231 (0.00%)	0/230 (0.00%)
# events	0	0	0	0	1	0	0
Immune system disorders							
Drug hypersensitivity † 1							
# participants affected / at risk	0/231 (0.00%)	0/230 (0.00%)	0/233 (0.00%)	1/230 (0.43%)	0/230 (0.00%)	0/231 (0.00%)	0/230 (0.00%)
# events	0	0	0	1	0	0	0
Hypersensitivity † 1							
# participants affected / at risk	0/231 (0.00%)	0/230 (0.00%)	0/233 (0.00%)	0/230 (0.00%)	0/230 (0.00%)	1/231 (0.43%)	0/230 (0.00%)
# events	0	0	0	0	0	1	0
Infections and infestations							
Appendicitis † 1							
# participants affected / at risk	0/231 (0.00%)	0/230 (0.00%)	0/233 (0.00%)	0/230 (0.00%)	1/230 (0.43%)	1/231 (0.43%)	0/230 (0.00%)
# events	0	0	0	0	1	1	0
Bronchopneumonia † 1							
# participants affected / at risk	0/231 (0.00%)	0/230 (0.00%)	0/233 (0.00%)	0/230 (0.00%)	1/230 (0.43%)	0/231 (0.00%)	0/230 (0.00%)
# events	0	0	0	0	1	0	0
Cellulitis † 1							
# participants affected / at risk	0/231 (0.00%)	0/230 (0.00%)	0/233 (0.00%)	0/230 (0.00%)	0/230 (0.00%)	1/231 (0.43%)	0/230 (0.00%)
# events	0	0	0	0	0	1	0
Dengue fever † 1							
# participants affected / at risk	0/231 (0.00%)	0/230 (0.00%)	0/233 (0.00%)	1/230 (0.43%)	0/230 (0.00%)	0/231 (0.00%)	0/230 (0.00%)
# events	0	0	0	1	0	0	0
Endocarditis † 1							

# participants affected / at risk	0/231 (0.00%)	0/230 (0.00%)	0/233 (0.00%)	0/230 (0.00%)	0/230 (0.00%)	0/231 (0.00%)	1/230 (0.43%)
# events	0	0	0	0	0	0	1
Escherichia urinary tract infection † 1							
# participants affected / at risk	0/231 (0.00%)	0/230 (0.00%)	0/233 (0.00%)	0/230 (0.00%)	0/230 (0.00%)	1/231 (0.43%)	0/230 (0.00%)
# events	0	0	0	0	0	1	0
Gastroenteritis † 1							
# participants affected / at risk	0/231 (0.00%)	0/230 (0.00%)	0/233 (0.00%)	0/230 (0.00%)	1/230 (0.43%)	0/231 (0.00%)	0/230 (0.00%)
# events	0	0	0	0	1	0	0
Gastroenteritis viral † 1							
# participants affected / at risk	0/231 (0.00%)	0/230 (0.00%)	0/233 (0.00%)	1/230 (0.43%)	0/230 (0.00%)	1/231 (0.43%)	0/230 (0.00%)
# events	0	0	0	1	0	1	0
Lobar pneumonia † 1							
# participants affected / at risk	0/231 (0.00%)	0/230 (0.00%)	0/233 (0.00%)	1/230 (0.43%)	0/230 (0.00%)	0/231 (0.00%)	0/230 (0.00%)
# events	0	0	0	1	0	0	0
Pneumonia † 1							
# participants affected / at risk	0/231 (0.00%)	1/230 (0.43%)	0/233 (0.00%)	1/230 (0.43%)	1/230 (0.43%)	0/231 (0.00%)	0/230 (0.00%)
# events	0	1	0	1	1	0	0
Tuberculosis † 1							
# participants affected / at risk	1/231 (0.43%)	0/230 (0.00%)	0/233 (0.00%)	0/230 (0.00%)	0/230 (0.00%)	0/231 (0.00%)	0/230 (0.00%)
# events	1	0	0	0	0	0	0
Wound infection † 1							
# participants affected / at risk	0/231 (0.00%)	0/230 (0.00%)	0/233 (0.00%)	0/230 (0.00%)	1/230 (0.43%)	0/231 (0.00%)	0/230 (0.00%)
# events	0	0	0	0	1	0	0
Injury, poisoning and procedural complications							
Foot fracture † 1							
# participants affected / at risk	1/231 (0.43%)	1/230 (0.43%)	0/233 (0.00%)	0/230 (0.00%)	0/230 (0.00%)	1/231 (0.43%)	0/230 (0.00%)
# events	1	1	0	0	0	1	0
Multiple injuries † 1							
# participants affected / at risk	0/231 (0.00%)	0/230 (0.00%)	1/233 (0.43%)	0/230 (0.00%)	1/230 (0.43%)	0/231 (0.00%)	0/230 (0.00%)
# events	0	0	1	0	1	0	0
Splenic haematoma † 1							
# participants affected / at risk	0/231 (0.00%)	0/230 (0.00%)	0/233 (0.00%)	0/230 (0.00%)	0/230 (0.00%)	1/231 (0.43%)	0/230 (0.00%)
# events	0	0	0	0	0	1	0
Tendon rupture † 1							
# participants affected / at risk	0/231 (0.00%)	1/230 (0.43%)	0/233 (0.00%)	0/230 (0.00%)	0/230 (0.00%)	0/231 (0.00%)	0/230 (0.00%)

# events	0	1	0	0	0	0	0
Upper limb fracture † 1							
# participants affected / at risk	0/231 (0.00%)	0/230 (0.00%)	0/233 (0.00%)	0/230 (0.00%)	0/230 (0.00%)	1/231 (0.43%)	0/230 (0.00%)
# events	0	0	0	0	0	1	0
Investigations							
Alanine aminotransferase increased † 1							
# participants affected / at risk	0/231 (0.00%)	0/230 (0.00%)	0/233 (0.00%)	0/230 (0.00%)	0/230 (0.00%)	0/231 (0.00%)	1/230 (0.43%)
# events	0	0	0	0	0	0	2
Aspartate aminotransferase increased † 1							
# participants affected / at risk	0/231 (0.00%)	0/230 (0.00%)	0/233 (0.00%)	0/230 (0.00%)	0/230 (0.00%)	0/231 (0.00%)	1/230 (0.43%)
# events	0	0	0	0	0	0	1
Metabolism and nutrition disorders							
Decreased appetite † 1							
# participants affected / at risk	0/231 (0.00%)	0/230 (0.00%)	1/233 (0.43%)	0/230 (0.00%)	0/230 (0.00%)	0/231 (0.00%)	0/230 (0.00%)
# events	0	0	1	0	0	0	0
Type 1 diabetes mellitus † 1							
# participants affected / at risk	0/231 (0.00%)	1/230 (0.43%)	0/233 (0.00%)	0/230 (0.00%)	0/230 (0.00%)	0/231 (0.00%)	0/230 (0.00%)
# events	0	1	0	0	0	0	0
Musculoskeletal and connective tissue disorders							
Back pain † 1							
# participants affected / at risk	0/231 (0.00%)	0/230 (0.00%)	0/233 (0.00%)	0/230 (0.00%)	0/230 (0.00%)	1/231 (0.43%)	0/230 (0.00%)
# events	0	0	0	0	0	1	0
Bursitis † 1							
# participants affected / at risk	0/231 (0.00%)	0/230 (0.00%)	0/233 (0.00%)	0/230 (0.00%)	1/230 (0.43%)	0/231 (0.00%)	0/230 (0.00%)
# events	0	0	0	0	1	0	0
Intervertebral disc protrusion † 1							
# participants affected / at risk	1/231 (0.43%)	0/230 (0.00%)	0/233 (0.00%)	0/230 (0.00%)	0/230 (0.00%)	0/231 (0.00%)	0/230 (0.00%)
# events	1	0	0	0	0	0	0
Osteoarthritis † 1							
# participants affected / at risk	0/231 (0.00%)	0/230 (0.00%)	0/233 (0.00%)	0/230 (0.00%)	0/230 (0.00%)	0/231 (0.00%)	1/230 (0.43%)
# events	0	0	0	0	0	0	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)							
Basal cell carcinoma † 1							
# participants affected / at risk	0/231 (0.00%)	1/230 (0.43%)	0/233 (0.00%)	0/230 (0.00%)	0/230 (0.00%)	0/231 (0.00%)	0/230 (0.00%)

# events	0	1	0	0	0	0	0
Bladder cancer † [1]							
# participants affected / at risk	0/231 (0.00%)	0/230 (0.00%)	0/233 (0.00%)	1/230 (0.43%)	0/230 (0.00%)	0/231 (0.00%)	0/230 (0.00%)
# events	0	0	0	1	0	0	0
Breast cancer † [1]							
# participants affected / at risk	0/231 (0.00%)	0/230 (0.00%)	0/233 (0.00%)	1/230 (0.43%)	0/230 (0.00%)	0/231 (0.00%)	0/230 (0.00%)
# events	0	0	0	1	0	0	0
Malignant melanoma † [1]							
# participants affected / at risk	0/231 (0.00%)	0/230 (0.00%)	0/233 (0.00%)	1/230 (0.43%)	0/230 (0.00%)	0/231 (0.00%)	0/230 (0.00%)
# events	0	0	0	1	0	0	0
Myelodysplastic syndrome † [1]							
# participants affected / at risk	0/231 (0.00%)	1/230 (0.43%)	0/233 (0.00%)	0/230 (0.00%)	0/230 (0.00%)	0/231 (0.00%)	0/230 (0.00%)
# events	0	1	0	0	0	0	0
Pancreatic carcinoma metastatic † [1]							
# participants affected / at risk	0/231 (0.00%)	0/230 (0.00%)	0/233 (0.00%)	0/230 (0.00%)	0/230 (0.00%)	1/231 (0.43%)	0/230 (0.00%)
# events	0	0	0	0	0	1	0
Prostate cancer † [1]							
# participants affected / at risk	0/231 (0.00%)	0/230 (0.00%)	0/233 (0.00%)	0/230 (0.00%)	1/230 (0.43%)	1/231 (0.43%)	1/230 (0.43%)
# events	0	0	0	0	1	1	1
Prostate cancer stage III † [1]							
# participants affected / at risk	0/231 (0.00%)	1/230 (0.43%)	0/233 (0.00%)	0/230 (0.00%)	0/230 (0.00%)	0/231 (0.00%)	0/230 (0.00%)
# events	0	1	0	0	0	0	0
Squamous cell carcinoma of skin † [1]							
# participants affected / at risk	1/231 (0.43%)	0/230 (0.00%)	0/233 (0.00%)	0/230 (0.00%)	0/230 (0.00%)	0/231 (0.00%)	0/230 (0.00%)
# events	1	0	0	0	0	0	0
Nervous system disorders							
Cerebral infarction † [1]							
# participants affected / at risk	0/231 (0.00%)	0/230 (0.00%)	1/233 (0.43%)	0/230 (0.00%)	0/230 (0.00%)	0/231 (0.00%)	0/230 (0.00%)
# events	0	0	1	0	0	0	0
Cerebral ischaemia † [1]							
# participants affected / at risk	1/231 (0.43%)	0/230 (0.00%)	0/233 (0.00%)	0/230 (0.00%)	0/230 (0.00%)	0/231 (0.00%)	0/230 (0.00%)
# events	1	0	0	0	0	0	0
Cerebrovascular accident † [1]							
# participants affected / at risk	0/231 (0.00%)	1/230 (0.43%)	0/233 (0.00%)	0/230 (0.00%)	0/230 (0.00%)	1/231 (0.43%)	0/230 (0.00%)
# events	0	1	0	0	0	1	0

Complicated migraine † 1							
# participants affected / at risk	0/231 (0.00%)	0/230 (0.00%)	0/233 (0.00%)	0/230 (0.00%)	1/230 (0.43%)	0/231 (0.00%)	0/230 (0.00%)
# events	0	0	0	0	1	0	0
Convulsion † 1							
# participants affected / at risk	1/231 (0.43%)	0/230 (0.00%)	0/233 (0.00%)	0/230 (0.00%)	0/230 (0.00%)	0/231 (0.00%)	0/230 (0.00%)
# events	1	0	0	0	0	0	0
Dizziness † 1							
# participants affected / at risk	0/231 (0.00%)	0/230 (0.00%)	1/233 (0.43%)	0/230 (0.00%)	0/230 (0.00%)	0/231 (0.00%)	0/230 (0.00%)
# events	0	0	1	0	0	0	0
Epilepsy † 1							
# participants affected / at risk	1/231 (0.43%)	0/230 (0.00%)	0/233 (0.00%)	0/230 (0.00%)	0/230 (0.00%)	0/231 (0.00%)	0/230 (0.00%)
# events	1	0	0	0	0	0	0
Haemorrhage intracranial † 1							
# participants affected / at risk	0/231 (0.00%)	0/230 (0.00%)	0/233 (0.00%)	0/230 (0.00%)	1/230 (0.43%)	0/231 (0.00%)	0/230 (0.00%)
# events	0	0	0	0	1	0	0
Headache † 1							
# participants affected / at risk	1/231 (0.43%)	0/230 (0.00%)	0/233 (0.00%)	0/230 (0.00%)	0/230 (0.00%)	0/231 (0.00%)	0/230 (0.00%)
# events	1	0	0	0	0	0	0
Sciatica † 1							
# participants affected / at risk	0/231 (0.00%)	0/230 (0.00%)	1/233 (0.43%)	0/230 (0.00%)	0/230 (0.00%)	0/231 (0.00%)	1/230 (0.43%)
# events	0	0	1	0	0	0	1
Psychiatric disorders							
Anxiety † 1							
# participants affected / at risk	0/231 (0.00%)	0/230 (0.00%)	0/233 (0.00%)	1/230 (0.43%)	0/230 (0.00%)	0/231 (0.00%)	0/230 (0.00%)
# events	0	0	0	1	0	0	0
Respiratory, thoracic and mediastinal disorders							
Asthma † 1							
# participants affected / at risk	0/231 (0.00%)	0/230 (0.00%)	0/233 (0.00%)	1/230 (0.43%)	1/230 (0.43%)	0/231 (0.00%)	0/230 (0.00%)
# events	0	0	0	1	2	0	0
Chronic obstructive pulmonary disease † 1							
# participants affected / at risk	0/231 (0.00%)	0/230 (0.00%)	0/233 (0.00%)	0/230 (0.00%)	0/230 (0.00%)	0/231 (0.00%)	1/230 (0.43%)
# events	0	0	0	0	0	0	1
Pulmonary embolism † 1							
# participants affected / at risk	0/231 (0.00%)	0/230 (0.00%)	0/233 (0.00%)	0/230 (0.00%)	1/230 (0.43%)	0/231 (0.00%)	0/230 (0.00%)
# events	0	0	0	0	1	0	0
Vascular disorders							

Arteriosclerosis † 1							
# participants affected / at risk	**2/231 (0.87%)**	**0/230 (0.00%)**	**0/233 (0.00%)**	**0/230 (0.00%)**	**0/230 (0.00%)**	**0/231 (0.00%)**	**0/230 (0.00%)**
# events	**2**	**0**	**0**	**0**	**0**	**0**	**0**
Deep vein thrombosis † 1							
# participants affected / at risk	**0/231 (0.00%)**	**0/230 (0.00%)**	**0/233 (0.00%)**	**0/230 (0.00%)**	**1/230 (0.43%)**	**0/231 (0.00%)**	**0/230 (0.00%)**
# events	**0**	**0**	**0**	**0**	**1**	**0**	**0**
Hypertensive emergency † 1							
# participants affected / at risk	**0/231 (0.00%)**	**1/230 (0.43%)**	**0/233 (0.00%)**	**0/230 (0.00%)**	**0/230 (0.00%)**	**0/231 (0.00%)**	**0/230 (0.00%)**
# events	**0**	**1**	**0**	**0**	**0**	**0**	**0**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA 13.1

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	Sitagliptin 100 mg and matching placebo to pioglitazone once daily for 54 weeks.
Pioglitazone 15 mg	Pioglitazone 15 mg and matching placebo to sitagliptin once daily for 54 weeks.
Pioglitazone 30 mg	Pioglitazone 30 mg and matching placebo to sitagliptin once daily for 54 weeks.
Pioglitazone 45 mg	Pioglitazone 45 mg and matching placebo to sitagliptin once daily for 54 weeks.
Sitagliptin 100 mg/ Pioglitazone 15 mg	Sitagliptin 100 mg and pioglitazone 15 mg once daily for 54 weeks.
Sitagliptin 100 mg/ Pioglitazone 30 mg	Sitagliptin 100 mg and pioglitazone 30 mg once daily for 54 weeks.
Sitagliptin 100 mg/ Pioglitazone 45 mg	Sitagliptin 100 mg and pioglitazone 45 mg once daily for 54 weeks.

Other Adverse Events

	Sitagliptin 100 mg	**Pioglitazone 15 mg**	**Pioglitazone 30 mg**	**Pioglitazone 45 mg**	**Sitagliptin 100 mg/ Pioglitazone 15 mg**	**Sitagliptin 100 mg/ Pioglitazone 30 mg**	**Sitagliptin 100 mg/ Pioglitazone 45 mg**
Total, other (not including serious) adverse events							
# participants affected / at risk	**60/231 (25.97%)**	**41/230 (17.83%)**	**45/233 (19.31%)**	**55/230 (23.91%)**	**48/230 (20.87%)**	**56/231 (24.24%)**	**46/230 (20.00%)**
Infections and infestations							
Nasopharyngitis † 1							

# participants affected / at risk	13/231 (5.63%)	10/230 (4.35%)	12/233 (5.15%)	9/230 (3.91%)	12/230 (5.22%)	15/231 (6.49%)	8/230 (3.48%)
# events	13	11	16	10	15	19	10
Upper respiratory tract infection † 1							
# participants affected / at risk	10/231 (4.33%)	6/230 (2.61%)	8/233 (3.43%)	12/230 (5.22%)	11/230 (4.78%)	9/231 (3.90%)	11/230 (4.78%)
# events	13	6	9	12	13	11	13
Metabolism and nutrition disorders							
Hypoglycaemia † 1							
# participants affected / at risk	25/231 (10.82%)	20/230 (8.70%)	22/233 (9.44%)	20/230 (8.70%)	20/230 (8.70%)	26/231 (11.26%)	24/230 (10.43%)
# events	57	30	78	81	45	100	93
Nervous system disorders							
Headache † 1							
# participants affected / at risk	17/231 (7.36%)	6/230 (2.61%)	9/233 (3.86%)	11/230 (4.78%)	8/230 (3.48%)	14/231 (6.06%)	5/230 (2.17%)
# events	18	8	9	12	8	18	5
Vascular disorders							
Hypertension † 1							
# participants affected / at risk	7/231 (3.03%)	5/230 (2.17%)	4/233 (1.72%)	10/230 (4.35%)	13/230 (5.65%)	6/231 (2.60%)	0/230 (0.00%)
# events	8	5	4	11	13	9	0

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA 13.1

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 sponsor must have the opportunity to review all proposed abstracts, manuscripts, or presentations regarding this study 60 days prior to submission for publication/presentation.

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 of Results:

Henry RR, Staels B, Fonseca VA, Chou MZ, Teng R, Golm GT, Langdon RB, Kaufman KD, Steinberg H, Goldstein BJ. Efficacy and safety of initial combination treatment with sitagliptin and pioglitazone--a factorial study. Diabetes Obes Metab. 2014 Mar;16(3):223-30. doi: 10.1111/dom.12194. Epub 2013 Aug 29.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00722371 History of Changes
Other Study ID Numbers:	0431-102 2008_522 (Other Identifier: Merck Study Number)
Study First Received:	July 22, 2008
Results First Received:	September 9, 2011
Last Updated:	March 23, 2015
Health Authority:	United States: Food and Drug Administration

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