Sitagliptin and Pioglitazone Mechanism of Action Study in Type 2 Diabetes Mellitus (0431-061)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

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

ClinicalTrials.gov Identifier:
NCT00511108

First received: August 2, 2007
Last updated: June 8, 2015
Last verified: June 2015
History of Changes

Purpose

A clinical study to determine the safety, efficacy and mechanism of action of sitagliptin alone and in combination with pioglitazone, in patients with type 2 diabetes mellitus who have inadequate glycemic (blood sugar) control.

Condition	Intervention	Phase
Type 2 Diabetes Mellitus (T2DM)	Drug: Comparator: sitagliptin phosphate Drug: Comparator: pioglitazone Drug: Comparator: placebo to pioglitazone Drug: Comparator: placebo to sitagliptin	Phase 1

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 I Double-Blind, Randomized, Placebo-Controlled Clinical Trial to Study the Safety, Efficacy, and Mechanism of Action of Sitagliptin and Pioglitazone in Patients With Type 2 Diabetes Mellitus Who Have Inadequate Glycemic Control on Diet and Exercise

Resource links provided by NLM:

MedlinePlus related topics: Diabetes Type 2

Drug Information available for: 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 Glucagon 3-hour Total Area Under the Curve (AUC) After 12 Weeks of Treatment [Time Frame: Baseline and 12 weeks] [Designated as safety issue: No]

  Glucagon concentration was measured at 9 points during an Meal Tolerance Test (MTT), at times -10, 0, 10, 20, 30, 60, 90, 120, and 180 minutes. Total AUC was calculated over 3 hours including all sample points starting from 0 minutes using the trapezoid method. The change from baseline reflects Week 12 total AUC minus the Week 0 total AUC.

- Percent Change From Baseline in Index of Static Beta-cell Sensitivity to Glucose After 12 Weeks of Treatment [Time Frame: Baseline and 12 weeks] [Designated as safety issue: No]

  Static sensitivity is a measure of the effect of glucose on beta cell secretion and is the ratio between the insulin secretion rate and glucose concentration above the threshold level at steady state. Percent change from baseline was calculated as the difference between index of static sensitivities at Week 12 and at baseline with respect to the index of static sensitivity at baseline times 100.

Secondary Outcome Measures:

- Change From Baseline in Glucose 5-hour Total AUC After 12 Weeks of Treatment [Time Frame: Baseline and 12 weeks] [Designated as safety issue: No]

  Glucose concentration was measured at 11 points during an Meal Tolerance Test (MTT), at times -10, 0, 10, 20, 30, 60, 90, 120, 180, 240, 300 minutes. Total AUC was calculated over 5 hours including all sample points starting from 0 minutes using the trapezoid method. The change from baseline reflects Week 12 total AUC minus the Week 0 total AUC.

Enrollment:	211
Study Start Date:	July 2007
Study Completion Date:	February 2009
Primary Completion Date:	February 2009 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: 1 Arm 1: drug	Drug: Comparator: sitagliptin phosphate sitagliptin phosphate 100 mg as oral tablets. Each patient will be administered 1 tablet once daily. Drug: Comparator: placebo to pioglitazone pioglitazone 30 mg placebos will be supplied as oral tablets. Each patient will be administered 1 tablet once daily.
Active Comparator: 2 Arm 2: active comparator	Drug: Comparator: pioglitazone pioglitazone 30 mg will be supplied as oral tablets. Each patient will be administered 1 tablet once daily. Drug: Comparator: placebo to sitagliptin sitagliptin phosphate 100 mg placebos will be supplied as oral tablets. Each patient will be administered 1 tablet once daily.
Experimental: 3 Arm 3: drug + active comparator	Drug: Comparator: sitagliptin phosphate sitagliptin phosphate 100 mg as oral tablets. Each patient will be administered 1 tablet once daily. Drug: Comparator: pioglitazone pioglitazone 30 mg will be supplied as oral tablets. Each patient will be administered 1 tablet once daily.
Placebo Comparator: 4 Arm 4: placebo comparator	Drug: Comparator: placebo to pioglitazone pioglitazone 30 mg placebos will be supplied as oral tablets. Each patient will be administered 1 tablet once daily. Drug: Comparator: placebo to sitagliptin sitagliptin phosphate 100 mg placebos will be supplied as oral tablets. Each patient will be administered 1 tablet once daily.

Eligibility

Ages Eligible for Study: 30 Years to 65 Years

Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- Patient has type 2 diabetes mellitus
- Male
- Female that is highly unlikely to become pregnant
- Patient is not on an antihyperglycemic agent (AHA) (hemoglobin A1c [A1C] 7-10%) or on oral single AHA or low-dose combination therapy (A1C 6.5-9.0%)

Exclusion Criteria:

- Patient has a history of type 1 diabetes mellitus or a history of ketoacidosis
- Patient has required insulin therapy within the past 12 weeks
- Patient is on or has been taking a Peroxisome Proliferator-Activated Receptor-gamma (PPAR -gamma) agent (i.e. Thiazolidinediones [TZDs]) within the prior 12 weeks of the screening visit.

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: NCT00511108

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:

Alba M, Ahrén B, Inzucchi SE, Guan Y, Mallick M, Xu L, O'Neill EA, Williams-Herman DE, Kaufman KD, Goldstein BJ. Sitagliptin and pioglitazone provide complementary effects on postprandial glucose and pancreatic islet cell function. Diabetes Obes Metab. 2013 Dec;15(12):1101-10. doi: 10.1111/dom.12145. Epub 2013 Jul 19.

Responsible Party: Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier: NCT00511108 History of Changes
Other Study ID Numbers: 0431-061 MK0431-061 2007_530
Study First Received: August 2, 2007
Results First Received: January 8, 2010
Last Updated: June 8, 2015
Health Authority: United States: Food and Drug Administration

Keywords provided by Merck Sharp & Dohme Corp.:
Type 2 Diabetes Mellitus (T2DM)

Additional relevant MeSH terms:

Diabetes Mellitus	Hormones
Diabetes Mellitus, Type 2	Hormones, Hormone Substitutes, and Hormone Antagonists

Endocrine System Diseases
Glucose Metabolism Disorders
Metabolic Diseases
Pioglitazone
Sitagliptin
Dipeptidyl-Peptidase IV Inhibitors
Enzyme Inhibitors
Hypoglycemic Agents
Incretins
Molecular Mechanisms of Pharmacological Action
Pharmacologic Actions
Physiological Effects of Drugs
Protease Inhibitors

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Results First Received: January 8, 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 (T2DM)
Interventions:	Drug: Comparator: sitagliptin phosphate Drug: Comparator: pioglitazone Drug: Comparator: placebo to pioglitazone Drug: Comparator: placebo to sitagliptin

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: 12-Sep-2007; Last Patient Last Visit: 24-Feb-2009

Forty-four medical clinics worldwide (17 in the United States, 20 in Europe, 4 in Australia, and 3 in Israel).

Pre-Assignment Details

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

Patients 30-65 years of age with type 2 diabetes mellitus (T2DM) with inadequate glycemic control (fasting plasma glucose [FPG] 130-260

mg/dL [7.2-14.4 mmol/L]) on diet and exercise alone were eligible for randomization.

Reporting Groups

	Description
Sitagliptin 100 mg	Includes patients receiving once-daily administration of sitagliptin 100 mg and matching placebo to pioglitazone 30 mg.
Pioglitazone 30 mg	Includes patients receiving once-daily administration of pioglitazone 30 mg and matching placebo to sitagliptin 100 mg.
Sitagliptin 100 mg + Pioglitazone 30 mg	Includes patients receiving once-daily administration of sitagliptin 100 mg and pioglitazone 30 mg.
Placebo	Includes patients receiving once-daily administration of matching placebo to sitagliptin 100 mg and matching placebo to pioglitazone 30 mg.

Participant Flow: Overall Study

	Sitagliptin 100 mg	Pioglitazone 30 mg	Sitagliptin 100 mg + Pioglitazone 30 mg	Placebo
STARTED	**52**	**54**	**52**	**53**
COMPLETED	**46**	**52**	**47**	**48**
NOT COMPLETED	**6**	**2**	**5**	**5**
Adverse Event	**2**	**0**	**1**	**2**
Lost to Follow-up	**0**	**2**	**1**	**0**
Physician Decision	**0**	**0**	**0**	**1**
Withdrawal by Subject	**4**	**0**	**3**	**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 100 mg	Includes patients receiving once-daily administration of sitagliptin 100 mg and matching placebo to pioglitazone 30 mg.
Pioglitazone 30 mg	Includes patients receiving once-daily administration of pioglitazone 30 mg and matching placebo to sitagliptin 100 mg.
Sitagliptin 100 mg + Pioglitazone 30 mg	Includes patients receiving once-daily administration of sitagliptin 100 mg and pioglitazone 30 mg.
Placebo	Includes patients receiving once-daily administration of matching placebo to sitagliptin 100 mg and matching placebo to pioglitazone 30 mg.
Total	Total of all reporting groups

Baseline Measures

	Sitagliptin 100 mg	Pioglitazone 30 mg	Sitagliptin 100 mg + Pioglitazone 30 mg	Placebo	Total
Number of Participants [units: participants]	52	54	52	53	211
Age [units: years] Mean (Standard Deviation)	54.6 (7.6)	53.4 (7.8)	53.3 (8.6)	53.3 (7.7)	53.6 (7.9)
Gender [units: participants]					
Female	24	31	18	21	94
Male	28	23	34	32	117
Race/Ethnicity, Customized [units: participants]					
White	45	43	49	48	185
Black	6	9	3	2	20
Asian	1	1	0	2	4
Other	0	1	0	1	2
Glucose 5-hour (hr) Total area under the curve (AUC) [1] [units: mg*hr/dL] Mean (Standard Deviation)	1179.9 (322.8)	1250.6 (349.6)	1276.0 (348.5)	1255.1 (290.9)	1240.4 (328.4)
Hemoglobin A1c (HbA1c) [units: Percent] Mean (Standard Deviation)	7.7 (0.8)	7.9 (0.9)	7.9 (0.9)	8.0 (1.1)	7.9 (1.0)

[1] Glucose concentration was measured at 11 points during a Meal Tolerance Test (MTT), at times -10, 0, 10, 20, 30, 60, 90, 120, 180, 240, 300 minutes. Total AUC was calculated over 5 hours including all sample points starting from 0 minutes using the trapezoid method.

The number of participants for the "Sitagliptin 100 mg + Pioglitazone 30 mg" arm is 51, making the total number of participants for this measure 210.

Outcome Measures

Hide All Outcome Measures

1. Primary: Change From Baseline in Glucagon 3-hour Total Area Under the Curve (AUC) After 12 Weeks of Treatment [Time Frame: Baseline and 12 weeks]

Measure Type	Primary
Measure Title	Change From Baseline in Glucagon 3-hour Total Area Under the Curve (AUC) After 12 Weeks of Treatment
Measure Description	Glucagon concentration was measured at 9 points during an Meal Tolerance Test (MTT), at times -10, 0, 10, 20, 30, 60, 90, 120, and 180 minutes. Total AUC was calculated over 3 hours including all sample points starting from 0 minutes using the trapezoid method. The change from baseline reflects Week 12 total AUC minus the Week 0 total AUC.
Time Frame	Baseline and 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.

The Full Analysis Set (FAS) included all patients with a baseline value and ≥1 post-baseline value for this outcome. For FAS patients with no data at Week 12, the last observed measurement was carried forward to Week 12.

Reporting Groups

	Description
Sitagliptin 100 mg	Includes patients receiving once-daily administration of sitagliptin 100 mg and matching placebo to pioglitazone 30 mg.
Pioglitazone 30 mg	Includes patients receiving once-daily administration of pioglitazone 30 mg and matching placebo to sitagliptin 100 mg.
Sitagliptin 100 mg + Pioglitazone 30 mg	Includes patients receiving once-daily administration of sitagliptin 100 mg and pioglitazone 30 mg.
Placebo	Includes patients receiving once-daily administration of matching placebo to sitagliptin 100 mg and matching placebo to pioglitazone 30 mg.

Measured Values

	Sitagliptin 100 mg	Pioglitazone 30 mg	Sitagliptin 100 mg + Pioglitazone 30 mg	Placebo
Number of Participants Analyzed [units: participants]	**48**	**47**	**42**	**39**
Change From Baseline in Glucagon 3-hour Total Area Under the Curve (AUC) After 12 Weeks of Treatment [units: pg*hr/mL] Least Squares Mean (95% Confidence Interval)	**-17.2 (-30.1 to -4.2)**	**-4.9 (-18.1 to 8.3)**	**-29.8 (-43.6 to -16.1)**	**12.5 (-1.9 to 26.9)**

Statistical Analysis 1 for Change From Baseline in Glucagon 3-hour Total Area Under the Curve (AUC) After 12 Weeks of Treatment

Groups [1]	Sitagliptin 100 mg vs. Placebo
Method [2]	ANCOVA
P Value [3]	0.002
Mean Difference (Net) [4]	-29.7
95% Confidence Interval	-48.7 to -10.6

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Model terms: treatment, prior diabetes pharmacotherapy (yes or no), and 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]	Other relevant estimation information:
	No text entered.

2. Primary: Percent Change From Baseline in Index of Static Beta-cell Sensitivity to Glucose After 12 Weeks of Treatment [Time Frame: Baseline and 12 weeks]

Measure Type	Primary
Measure Title	Percent Change From Baseline in Index of Static Beta-cell Sensitivity to Glucose After 12 Weeks of Treatment
Measure Description	Static sensitivity is a measure of the effect of glucose on beta cell secretion and is the ratio between the insulin secretion rate and glucose concentration above the threshold level at steady state. Percent change from baseline was calculated as the difference between index of static sensitivities at Week 12 and at baseline with respect to the index of static sensitivity at baseline times 100.
Time Frame	Baseline and 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.
The Full Analysis Set (FAS) included all patients with a baseline value and ≥1 post-baseline value for this outcome. For FAS patients with no data at Week 12, the last observed measurement was carried forward to Week 12.

Reporting Groups

	Description
Sitagliptin 100 mg	Includes patients receiving once-daily administration of sitagliptin 100 mg and matching placebo to pioglitazone 30 mg.
Pioglitazone 30 mg	Includes patients receiving once-daily administration of pioglitazone 30 mg and matching placebo to sitagliptin 100 mg.
Sitagliptin 100 mg + Pioglitazone 30 mg	Includes patients receiving once-daily administration of sitagliptin 100 mg and pioglitazone 30 mg.
Placebo	Includes patients receiving once-daily administration of matching placebo to sitagliptin 100 mg and matching placebo to pioglitazone 30 mg.

Measured Values

	Sitagliptin 100 mg	**Pioglitazone 30 mg**	**Sitagliptin 100 mg + Pioglitazone 30 mg**	**Placebo**
Number of Participants Analyzed [units: participants]	**38**	**34**	**27**	**33**
Percent Change From Baseline in Index of Static Beta-cell Sensitivity to Glucose After 12 Weeks of Treatment [units: Percent Change] Least Squares Mean (95% Confidence Interval)	**71.5 (46.8 to 100.3)**	**27.0 (7.8 to 49.7)**	**125.2 (87.2 to 171.0)**	**-2.3 (-17.4 to 15.5)**

Statistical Analysis 1 for Percent Change From Baseline in Index of Static Beta-cell Sensitivity to Glucose After 12 Weeks of Treatment

Groups [1]	Sitagliptin 100 mg vs. Placebo
Method [2]	ANCOVA
P Value [3]	<0.001
Geometric Mean Difference [4]	73.8

95% Confidence Interval	44.2 to 104.4

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Model terms: treatment, prior diabetes pharmacotherapy (yes or no), and log-scaled 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]	Other relevant estimation information:
	The outcome was analyzed by ANCOVA on the log scale. Results have been back-transformed to the original scale.

3. Secondary: Change From Baseline in Glucose 5-hour Total AUC After 12 Weeks of Treatment [Time Frame: Baseline and 12 weeks]

Measure Type	Secondary
Measure Title	Change From Baseline in Glucose 5-hour Total AUC After 12 Weeks of Treatment
Measure Description	Glucose concentration was measured at 11 points during an Meal Tolerance Test (MTT), at times -10, 0, 10, 20, 30, 60, 90, 120, 180, 240, 300 minutes. Total AUC was calculated over 5 hours including all sample points starting from 0 minutes using the trapezoid method. The change from baseline reflects Week 12 total AUC minus the Week 0 total AUC.
Time Frame	Baseline and 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.
The Full Analysis Set (FAS) included all patients with a baseline value and ≥1 post-baseline value for this outcome. For FAS patients with no data at Week 12, the last observed measurement was carried forward to Week 12.

Reporting Groups

	Description
Sitagliptin 100 mg	Includes patients receiving once-daily administration of sitagliptin 100 mg and matching placebo to pioglitazone 30 mg.
Pioglitazone 30 mg	Includes patients receiving once-daily administration of pioglitazone 30 mg and matching placebo to sitagliptin 100 mg.
Sitagliptin 100 mg + Pioglitazone 30 mg	Includes patients receiving once-daily administration of sitagliptin 100 mg and pioglitazone 30 mg.
Placebo	Includes patients receiving once-daily administration of matching placebo to sitagliptin 100 mg and matching placebo to pioglitazone 30 mg.

Measured Values

	Sitagliptin 100 mg	**Pioglitazone 30 mg**	**Sitagliptin 100 mg + Pioglitazone 30 mg**	**Placebo**
Number of Participants Analyzed [units: participants]	**48**	**49**	**44**	**42**

Change From Baseline in Glucose 5-hour Total AUC After 12 Weeks of Treatment [units: mg*hr/dL] Least Squares Mean (95% Confidence Interval)	**-209.8 (-281.6 to -138.0)**	**-245.6 (-316.6 to -174.6)**	**-389.2 (-463.6 to -314.7)**	**18.6 (-58.2 to 95.4)**

Statistical Analysis 1 for Change From Baseline in Glucose 5-hour Total AUC After 12 Weeks of Treatment

Groups [1]	Sitagliptin 100 mg + Pioglitazone 30 mg vs. Placebo
Method [2]	ANCOVA
P Value [3]	<0.001
Mean Difference (Net) [4]	-407.8
95% Confidence Interval	-513.4 to -302.1

[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:
	Model terms: treatment, prior diabetes pharmacotherapy (yes or no), and 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]	Other relevant estimation information:
	No text entered.

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	Weeks 0-12
Additional Description	No text entered.

Reporting Groups

	Description
Sitagliptin 100 mg	Includes patients receiving once-daily administration of sitagliptin 100 mg and matching placebo to pioglitazone 30 mg.
Pioglitazone 30 mg	Includes patients receiving once-daily administration of pioglitazone 30 mg and matching placebo to sitagliptin 100 mg.
Sitagliptin 100 mg + Pioglitazone 30 mg	Includes patients receiving once-daily administration of sitagliptin 100 mg and pioglitazone 30 mg.
Placebo	Includes patients receiving once-daily administration of matching placebo to sitagliptin 100 mg and matching placebo to pioglitazone 30 mg.

Serious Adverse Events

	Sitagliptin	**Pioglitazone**	**Sitagliptin 100 mg +**	

	100 mg	30 mg	Pioglitazone 30 mg	Placebo
Total, serious adverse events				
# participants affected / at risk	**1/52 (1.92%)**	**0/54 (0.00%)**	**1/52 (1.92%)**	**0/53 (0.00%)**
Injury, poisoning and procedural complications				
Tibia fracture * 1				
# participants affected / at risk	**0/52 (0.00%)**	**0/54 (0.00%)**	**1/52 (1.92%)**	**0/53 (0.00%)**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
Breast cancer * 1				
# participants affected / at risk	**1/52 (1.92%)**	**0/54 (0.00%)**	**0/52 (0.00%)**	**0/53 (0.00%)**

* Events were collected by non-systematic assessment

1 Term from vocabulary, MedDRA 11.1

Other Adverse Events

Hide Other Adverse Events

Time Frame	Weeks 0-12
Additional Description	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Sitagliptin 100 mg	Includes patients receiving once-daily administration of sitagliptin 100 mg and matching placebo to pioglitazone 30 mg.
Pioglitazone 30 mg	Includes patients receiving once-daily administration of pioglitazone 30 mg and matching placebo to sitagliptin 100 mg.
Sitagliptin 100 mg + Pioglitazone 30 mg	Includes patients receiving once-daily administration of sitagliptin 100 mg and pioglitazone 30 mg.
Placebo	Includes patients receiving once-daily administration of matching placebo to sitagliptin 100 mg and matching placebo to pioglitazone 30 mg.

Other Adverse Events

	Sitagliptin 100 mg	Pioglitazone 30 mg	Sitagliptin 100 mg + Pioglitazone 30 mg	Placebo
Total, other (not including serious) adverse events				

# participants affected / at risk	**3/52 (5.77%)**	**3/54 (5.56%)**	**0/52 (0.00%)**	**9/53 (16.98%)**
Infections and infestations				
Upper respiratory tract infection * 1				
# participants affected / at risk	**0/52 (0.00%)**	**3/54 (5.56%)**	**0/52 (0.00%)**	**3/53 (5.66%)**
Investigations				
Blood glucose increased * 1				
# participants affected / at risk	**0/52 (0.00%)**	**0/54 (0.00%)**	**0/52 (0.00%)**	**3/53 (5.66%)**
Metabolism and nutrition disorders				
Hyperglycaemia * 1				
# participants affected / at risk	**3/52 (5.77%)**	**0/54 (0.00%)**	**0/52 (0.00%)**	**0/53 (0.00%)**
Nervous system disorders				
Headache * 1				
# participants affected / at risk	**0/52 (0.00%)**	**0/54 (0.00%)**	**0/52 (0.00%)**	**3/53 (5.66%)**

* 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

Publications of Results:

Alba M, Ahrén B, Inzucchi SE, Guan Y, Mallick M, Xu L, O'Neill EA, Williams-Herman DE, Kaufman KD, Goldstein BJ. Sitagliptin and pioglitazone provide complementary effects on postprandial glucose and pancreatic islet cell function. Diabetes Obes Metab. 2013 Dec;15(12):1101-10. doi: 10.1111/dom.12145. Epub 2013 Jul 19.

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Study First Received:	August 2, 2007
Results First Received:	January 8, 2010
Last Updated:	June 8, 2015
Health Authority:	United States: Food and Drug Administration

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