A Study to Evaluate the Safety and Efficacy of Sitagliptin 100 mg in Participants With Type 2 Diabetes Mellitus Who Have Inadequate Glycemic Control (MK-0431-229)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

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

ClinicalTrials.gov Identifier:
NCT01076075

First received: February 24, 2010
Last updated: January 21, 2016
Last verified: January 2016
History of Changes

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Purpose

This study will evaluate whether the addition of Sitagliptin treatment provides a greater decrease in A1C levels compared to placebo in participants with inadequate glycemic control on sulfonylurea and metformin combination therapy.

Condition	Intervention	Phase
Type 2 Diabetes Mellitus	Drug: Sitagliptin phosphate Drug: Comparator: placebo to pioglitazone Drug: Comparator: placebo to Sitagliptin Drug: Comparator: pioglitazone Drug: Glimepiride or gliclazide Drug: Metformin Drug: Pioglitazone rescue therapy	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, Clinical Trial to Evaluate the Safety and Efficacy of the Addition of Sitagliptin in Patients With Type 2 Diabetes Mellitus Who Have Inadequate Glycemic Control on a Sulfonylurea in Combination With Metformin

Resource links provided by NLM:

MedlinePlus related topics: Diabetes Type 2

Drug Information available for: Metformin Metformin hydrochloride Glimepiride 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 (%) at Week 24 [Time Frame: Baseline and Week 24] [Designated as safety issue: No]

  Change from baseline reflects the Week 24 value minus the baseline value. A1C represents the percentage of glycosylated hemoglobin.

- Number of Participants With One or More Adverse Events (AEs) - Week 0 to Week 54 [Time Frame: Week 0 to Week 54] [Designated as safety issue: Yes]
- Number of Participants Discontinuing Study Drug Due to An Adverse Event [Time Frame: Week 0 to Week 54] [Designated as safety issue: Yes]

Secondary Outcome Measures:

- Change From Baseline in 2-hour Post-Meal Glucose at Week 24 [Time Frame: Baseline and Week 24] [Designated as safety issue: No]

  Change from baseline reflects the Week 24 value minus the baseline value. Two-hour post-meal glucose was measured following a standard meal.

- Change From Baseline in Fasting Plasma Glucose at Week 24 [Time Frame: Baseline to Week 24] [Designated as safety issue: No]

  Change from baseline reflects the Week 24 value minus the baseline value.

Enrollment:	427
Study Start Date:	June 2010
Study Completion Date:	January 2012
Primary Completion Date:	July 2011 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Active Comparator: placebo/pioglitazone Phase A (Weeks 0-24): placebo to Sitagliptin 100 mg; Phase B (Weeks 24-54): placebo to Sitagliptin 100 mg + pioglitazone 30 mg	Drug: Comparator: placebo to Sitagliptin Phase A (Weeks 0-24): placebo to Sitagliptin 100 mg once a day for 24 weeks; Phase B (Weeks 24-54): placebo to Sitagliptin once a day for 30 weeks Drug: Comparator: pioglitazone Phase B (Weeks 24-54): pioglitazone 30 mg once a day for 30 weeks Other Name: Actos; Drug: Glimepiride or gliclazide Phase A (Weeks 0-24): stable dose, as prescribed by investigator, of glimepiride or gliclazide; Phase B (Weeks 24-54): stable dose, as prescribed by investigator, of glimepiride or gliclazide Drug: Metformin Phase A (Weeks 0-24): stable dose, as prescribed by investigator, of metformin; Phase B (Weeks 24-54): stable dose, as prescribed by investigator, of metformin Drug: Pioglitazone rescue therapy Phase A (Weeks 0-24): participants not meeting specific glycemic goals will receive pioglitazone (open label) at a dose determined by the investigator. These participants will not initiate Phase B (Weeks 24-54) double blind pioglitazone. Other Name: Actos
Experimental: Sitagliptin Phase A (Weeks 0-24): Sitagliptin 100 mg; Phase B (Weeks 24-54): Sitagliptin 100 mg + placebo to pioglitazone	Drug: Sitagliptin phosphate Phase A (Weeks 0-24): Sitagliptin 100 mg once a day for 24 weeks; Phase B (Weeks 24-54): Sitagliptin 100 mg once a day for 30 weeks Other Name: Januvia Drug: Comparator: placebo to pioglitazone Phase B (Weeks 24-54): placebo to pioglitazone 30 mg once a day for 30 weeks

	Drug: Glimepiride or gliclazide Phase A (Weeks 0-24): stable dose, as prescribed by investigator, of glimepiride or gliclazide; Phase B (Weeks 24-54): stable dose, as prescribed by investigator, of glimepiride or gliclazide Drug: Metformin Phase A (Weeks 0-24): stable dose, as prescribed by investigator, of metformin; Phase B (Weeks 24-54): stable dose, as prescribed by investigator, of metformin Drug: Pioglitazone rescue therapy Phase A (Weeks 0-24): participants not meeting specific glycemic goals will receive pioglitazone (open label) at a dose determined by the investigator. These participants will not initiate Phase B (Weeks 24-54) double blind pioglitazone. Other Name: Actos

Eligibility

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

Criteria

Inclusion Criteria:

- Type 2 diabetes mellitus
- Hemoglobin A1C of ≥7.5% and ≤10.5%
- Currently taking a stable dose of metformin (at least 1500 mg/day) and either glimepiride (at least 2 mg/day) or gliclazide (at least 50% of maximum registered dose) for at least 10 weeks prior to study start
- Male, or a female who is highly unlikely to conceive

Exclusion Criteria:

- Type 1 diabetes mellitus or ketoacidosis
- Taking a dipeptidyl peptidase-4 (DPP-4) inhibitor (such as sitagliptin) or a glucagon-like peptide-1 (GLP-1) mimetic (such as exenatide or liraglutide) or required insulin therapy within 12 weeks prior to study start
- On a weight loss program not in the maintenance phase or on a weight loss medication
- History of liver disease, heart failure, heart disease, stroke, high blood pressure, blood disorders, or cancer
- HIV positive
- Pregnant

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: NCT01076075

Sponsors and Collaborators

Merck Sharp & Dohme Corp.

Investigators

Study Director: Medical Monitor Merck Sharp & Dohme Corp.

More Information

Publications:

Moses RG, Round E, Shentu Y, Golm GT, O'neill EA, Gantz I, Engel SS, Kaufman KD, Goldstein BJ. A randomized clinical trial evaluating the safety and efficacy of sitagliptin added to the combination of sulfonylurea and metformin in patients with type 2 diabetes mellitus and inadequate glycemic control. J Diabetes. 2015 Dec 1. doi: 10.1111/1753-0407.12351. [Epub ahead of print]

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT01076075 History of Changes
Other Study ID Numbers:	0431-229 2010_513 MK-0431-229
Study First Received:	February 24, 2010
Results First Received:	June 28, 2012
Last Updated:	January 21, 2016
Health Authority:	Malaysia: Ministry of Health Australia: Department of Health and Ageing Therapeutic Goods Administration India: Ministry of Health

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

Additional relevant MeSH terms:

Diabetes Mellitus	Enzyme Inhibitors
Diabetes Mellitus, Type 2	Hormones
Endocrine System Diseases	Hormones, Hormone Substitutes, and Hormone Antagonists
Glucose Metabolism Disorders	Hypoglycemic Agents
Metabolic Diseases	Immunologic Factors
Gliclazide	Immunosuppressive Agents
Glimepiride	Incretins
Metformin	Molecular Mechanisms of Pharmacological Action
Pioglitazone	Pharmacologic Actions
Sitagliptin	Physiological Effects of Drugs
Anti-Arrhythmia Agents	Protease Inhibitors
Cardiovascular Agents	Therapeutic Uses
Dipeptidyl-Peptidase IV Inhibitors	

ClinicalTrials.gov processed this record on April 13, 2016

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Trial record **1 of 1** for: NCT01076075

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Results First Received: June 28, 2012

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: Comparator: placebo to pioglitazone Drug: Comparator: placebo to Sitagliptin Drug: Comparator: pioglitazone Drug: Glimepiride or gliclazide Drug: Metformin Drug: Pioglitazone rescue therapy

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

762 participants were screened, 335 participants were excluded, and 427 participants were randomized. There was a single-blind run-in prior to randomization.

Reporting Groups

	Description
Sitagliptin	Phase A (Weeks 0-24): Sitagliptin 100 mg; Phase B (Weeks 24-54): Sitagliptin 100 mg + Placebo to Pioglitazone
Placebo/Pioglitazone	Phase A (Weeks 0-24): Placebo to Sitagliptin 100 mg; Phase B (Weeks 24-54): Placebo to Sitagliptin 100 mg + Pioglitazone 30 mg

Participant Flow: Overall Study

	Sitagliptin	Placebo/Pioglitazone
STARTED	**213** [1]	**214** [2]
Completed Phase A	**199**	**189**
COMPLETED	**172**	**167**
NOT COMPLETED	**41**	**47**
Adverse Event	**3**	**9**
Lack of Efficacy	**5**	**4**
Lost to Follow-up	**6**	**5**
other	**19**	**9**
Protocol Violation	**0**	**1**
Withdrawal by Subject	**8**	**19**

[1] 3 participants were excluded from safety and efficacy analyses due to one site's non-compliance
[2] 2 participants were excluded from safety and efficacy analyses due to one site's non-compliance

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	Phase A (Weeks 0-24): Sitagliptin 100 mg; Phase B (Weeks 24-54): Sitagliptin 100 mg + Placebo to Pioglitazone
Placebo/Pioglitazone	Phase A (Weeks 0-24): Placebo to Sitagliptin 100 mg; Phase B (Weeks 24-54): Placebo to Sitagliptin 100 mg + Pioglitazone 30 mg
Total	Total of all reporting groups

Baseline Measures

	Sitagliptin	Placebo/Pioglitazone	Total

Number of Participants [units: participants]	**210**	**212**	**422**
Age [1] [units: years] Mean (Standard Deviation)	**54.4 (9.6)**	**55.4 (10.2)**	**54.9 (9.9)**
Gender [1] [units: participants]			
Female	**115**	**114**	**229**
Male	**95**	**98**	**193**
Hemoglobin A1C [1] [units: Percentage of glycosylated hemoglobin] Mean (Standard Deviation)	**8.4 (0.8)**	**8.4 (0.9)**	**8.4 (0.8)**
2-Hour Post-Meal Glucose [2] [units: mg/dL] Mean (Standard Deviation)	**240.3 (60.6)**	**243.3 (68.8)**	**241.8 (64.8)**
Fasting Plasma Glucose [1] [units: mg/dL] Mean (Standard Deviation)	**164.8 (40.8)**	**165.0 (43.9)**	**164.9 (42.4)**

[1] Number of Baseline Participants for Sitagliptin (210) and for Placebo/Pioglitazone (212). Five participants (Sitagliptin: 3, Placebo/Pioglitazone: 2) were excluded from analyses due to one site's non-compliance.

[2] Number of Baseline Participants for Sitagliptin (202) and for Placebo/Pioglitazone (208). Five participants (Sitagliptin: 3, Placebo/Pioglitazone: 2) were excluded from analyses due to one site's non-compliance.

Outcome Measures

Hide All Outcome Measures

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

Measure Type	Primary
Measure Title	Change From Baseline in Hemoglobin A1C (%) at Week 24
Measure Description	Change from baseline reflects the Week 24 value minus the baseline value. 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.
The Full Analysis Set Population received at least one dose of study treatment and had baseline data and at least one post-baseline treatment endpoint observation for the analysis endpoint. Missing data were imputed using last observation carried forward (LOCF). Five participants were excluded from analyses due to one site's non-compliance.

Reporting Groups

	Description
Sitagliptin	Phase A (Weeks 0-24): Sitagliptin 100 mg

Placebo/Pioglitazone	Phase A (Week 0-24): Placebo to Sitagliptin 100 mg

Measured Values

	Sitagliptin	Placebo/Pioglitazone
Number of Participants Analyzed [units: participants]	**203**	**202**
Change From Baseline in Hemoglobin A1C (%) at Week 24 [units: Percentage of glycosylated hemoglobin] Least Squares Mean (95% Confidence Interval)	**-0.84 (-0.97 to -0.71)**	**-0.16 (-0.28 to -0.03)**

Statistical Analysis 1 for Change From Baseline in Hemoglobin A1C (%) at Week 24

Groups [1]	All groups
Method [2]	ANCOVA
P Value [3]	<0.001
Difference in Least Squares Means [4]	-0.68
95% Confidence Interval	-0.87 to -0.50

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	Pairwise comparison - Sitagliptin vs. Placebo, using the difference in the Least Squares Means.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Based on an ANCOVA model controlling for treatment, stratum (type of sulfonylurea) and baseline value.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

2. Primary: Number of Participants With One or More Adverse Events (AEs) - Week 0 to Week 54 [Time Frame: Week 0 to Week 54]

Measure Type	Primary
Measure Title	Number of Participants With One or More Adverse Events (AEs) - Week 0 to Week 54
Measure Description	No text entered.
Time Frame	Week 0 to Week 54
Safety Issue	Yes

Population Description

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

The All Patients as Treated Population took at least one dose of study drug. Participants received glycemic rescue medication if they met specific glycemic goals up to Week 24. Adverse events include those that occurred prior to a receiving rescue medication. Five participants were excluded from analyses due to 1 site's non-compliance.

Reporting Groups

	Description
Sitagliptin	Phase A (Weeks 0-24): Sitagliptin 100 mg; Phase B (Weeks 24-54): Sitagliptin 100 mg + Placebo to Pioglitazone
Placebo/Pioglitazone	Phase A (Weeks 0-24: Placebo to Sitagliptin 100 mg; Phase B (Weeks 24-54): Placebo to Sitagliptin 100 mg + Pioglitazone 30 mg

Measured Values

	Sitagliptin	Placebo/Pioglitazone
Number of Participants Analyzed [units: participants]	**210**	**212**
Number of Participants With One or More Adverse Events (AEs) - Week 0 to Week 54 [units: participants]	**120**	**122**

No statistical analysis provided for Number of Participants With One or More Adverse Events (AEs) - Week 0 to Week 54

3. Primary: Number of Participants Discontinuing Study Drug Due to An Adverse Event [Time Frame: Week 0 to Week 54]

Measure Type	Primary
Measure Title	Number of Participants Discontinuing Study Drug Due to An Adverse Event
Measure Description	No text entered.
Time Frame	Week 0 to Week 54
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The All Patients as Treated Population took at least 1 dose of study drug. Participants received glycemic rescue medication if they met specific glycemic goals up to Week 24. Participants discontinued due to adverse events are reported regardless of rescue medication. Five participants were excluded from analyses due to 1 site's non-compliance.

Reporting Groups

	Description
Sitagliptin	Phase A (Weeks 0-24): Sitagliptin 100 mg; Phase B (Weeks 24-54): Sitagliptin 100 mg + Placebo to Pioglitazone
Placebo/Pioglitazone	Phase A (Weeks 0-24: Placebo to Sitagliptin 100 mg; Phase B (Weeks 24-54): Placebo to Sitagliptin 100 mg + Pioglitazone 30 mg

Measured Values

	Sitagliptin	Placebo/Pioglitazone
Number of Participants Analyzed	**210**	**212**

[units: participants]		
Number of Participants Discontinuing Study Drug Due to An Adverse Event **[units: participants]**	**3**	**9**

No statistical analysis provided for Number of Participants Discontinuing Study Drug Due to An Adverse Event

4. Secondary: Change From Baseline in 2-hour Post-Meal Glucose at Week 24 [Time Frame: Baseline and Week 24]

Measure Type	Secondary
Measure Title	Change From Baseline in 2-hour Post-Meal Glucose at Week 24
Measure Description	Change from baseline reflects the Week 24 value minus the baseline value. Two-hour post-meal glucose was measured following a standard meal.
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.
The Full Analysis Set Population received at least one dose of study treatment and had baseline data and at least one post-baseline treatment endpoint observation for the analysis endpoint. Missing data were imputed using last observation carried forward (LOCF). Five participants were excluded from analyses due to one site's non-compliance.

Reporting Groups

	Description
Sitagliptin	Phase A (Week 0-24): Sitagliptin 100 mg
Placebo/Pioglitazone	Phase A (Week 0-24): Placebo to Sitagliptin 100 mg

Measured Values

	Sitagliptin	**Placebo/Pioglitazone**
Number of Participants Analyzed **[units: participants]**	**184**	**183**
Change From Baseline in 2-hour Post-Meal Glucose at Week 24 **[units: mg/dL]** **Least Squares Mean (95% Confidence Interval)**	**-36.8 (-45.2 to -28.4)**	**-3.3 (-11.7 to 5.0)**

Statistical Analysis 1 for Change From Baseline in 2-hour Post-Meal Glucose at Week 24

Groups [1]	All groups
Method [2]	ANCOVA
P Value [3]	<0.001
Difference in Least Squares Means [4]	-33.5

95% Confidence Interval	-45.3 to -21.7

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	Pairwise comparison - Sitagliptin vs. Placebo, difference in the Least Squares Means.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Based on an ANCOVA model controlling for treatment, stratum (type of sulfonylurea) and baseline value.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

5. Secondary: Change From Baseline in Fasting Plasma Glucose at Week 24 [Time Frame: Baseline to Week 24]

Measure Type	Secondary
Measure Title	Change From Baseline in Fasting Plasma Glucose at Week 24
Measure Description	Change from baseline reflects the Week 24 value minus the baseline value.
Time Frame	Baseline to 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.
The Full Analysis Set Population received at least one dose of study treatment and had baseline data and at least one post-baseline treatment endpoint observation for the analysis endpoint. Missing data were imputed using last observation carried forward (LOCF). Five participants were excluded from analyses due to one site's non-compliance.

Reporting Groups

	Description
Sitagliptin	Phase A (Week 0-24): Sitagliptin 100 mg
Placebo/Pioglitazone	Phase A (Week 0-24): Placebo to Sitagliptin 100 mg

Measured Values

	Sitagliptin	**Placebo/Pioglitazone**
Number of Participants Analyzed [units: participants]	**204**	**203**
Change From Baseline in Fasting Plasma Glucose at Week 24 [units: mg/dL] Least Squares Mean (95% Confidence Interval)	**-13.2 (-18.8 to -7.7)**	**5.3 (-0.2 to 10.9)**

Statistical Analysis 1 for Change From Baseline in Fasting Plasma Glucose at Week 24

Groups [1]	All groups
Method [2]	ANCOVA
P Value [3]	<0.001
Difference in Least Squares Means [4]	-18.6
95% Confidence Interval	-26.4 to -10.7

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	Pairwise comparison - Sitagliptin vs. Placebo, using the difference in the Least Squares Means.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Based on an ANCOVA model controlling for treatment, stratum (type of sulfonylurea) and baseline value.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	Week 0 to Week 54
Additional Description	All Patients as Treated Population took at least 1 dose of study drug. Participants received glycemic rescue medication if they met specific glycemic goals up to Week 24. Serious AEs (SAEs) are reported regardless of rescue medication. Other AEs are those that occurred prior to rescue medication. Five participants were excluded from analyses.

Reporting Groups

	Description
Sitagliptin	Phase A (Weeks 0-24): Sitagliptin 100 mg; Phase B (Weeks 24-54): Sitagliptin 100 mg + Placebo to Pioglitazone
Placebo/Pioglitazone	Phase A (Weeks 0-24): Placebo to Sitagliptin 100 mg; Phase B (Weeks 24-54): Placebo to Sitagliptin 100 mg + Pioglitazone 30 mg

Serious Adverse Events

	Sitagliptin	**Placebo/Pioglitazone**
Total, serious adverse events		
# participants affected / at risk	**6/210 (2.86%)**	**9/212 (4.25%)**
Cardiac disorders		
Angina pectoris † 1		

# participants affected / at risk	0/210 (0.00%)	1/212 (0.47%)
# events	0	1
Atrial flutter † 1		
# participants affected / at risk	1/210 (0.48%)	0/212 (0.00%)
# events	1	0
Hepatobiliary disorders		
Cholelithiasis † 1		
# participants affected / at risk	1/210 (0.48%)	0/212 (0.00%)
# events	1	0
Infections and infestations		
Abscess limb † 1		
# participants affected / at risk	0/210 (0.00%)	1/212 (0.47%)
# events	0	1
Appendicitis † 1		
# participants affected / at risk	0/210 (0.00%)	1/212 (0.47%)
# events	0	1
Cellulitis † 1		
# participants affected / at risk	0/210 (0.00%)	1/212 (0.47%)
# events	0	1
Gangrene † 1		
# participants affected / at risk	1/210 (0.48%)	0/212 (0.00%)
# events	1	0
Tooth abscess † 1		
# participants affected / at risk	1/210 (0.48%)	0/212 (0.00%)
# events	1	0
Urosepsis † 1		
# participants affected / at risk	0/210 (0.00%)	1/212 (0.47%)
# events	0	1
Injury, poisoning and procedural complications		
Joint dislocation † 1		
# participants affected / at risk	0/210 (0.00%)	1/212 (0.47%)
# events	0	1
Skull fracture † 1		
# participants affected / at risk	0/210 (0.00%)	1/212 (0.47%)
# events	0	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Prostate cancer † 1		
# participants affected / at risk	0/210 (0.00%)	1/212 (0.47%)
# events	0	1
Nervous system disorders		
Ischaemic stroke † 1		
# participants affected / at risk	1/210 (0.48%)	0/212 (0.00%)
# events	1	0
Renal and urinary disorders		

Bladder neck obstruction † 1		
# participants affected / at risk	**0/210 (0.00%)**	**1/212 (0.47%)**
# events	**0**	**1**
Renal colic † 1		
# participants affected / at risk	**0/210 (0.00%)**	**1/212 (0.47%)**
# events	**0**	**1**
Respiratory, thoracic and mediastinal disorders		
Nasal inflammation † 1		
# participants affected / at risk	**1/210 (0.48%)**	**0/212 (0.00%)**
# events	**1**	**0**
Pneumonitis † 1		
# participants affected / at risk	**0/210 (0.00%)**	**1/212 (0.47%)**
# events	**0**	**1**
Vascular disorders		
Hypertensive crisis † 1		
# participants affected / at risk	**0/210 (0.00%)**	**1/212 (0.47%)**
# events	**0**	**1**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA 14.1

Other Adverse Events

Hide Other Adverse Events

Time Frame	Week 0 to Week 54
Additional Description	All Patients as Treated Population took at least 1 dose of study drug. Participants received glycemic rescue medication if they met specific glycemic goals up to Week 24. Serious AEs (SAEs) are reported regardless of rescue medication. Other AEs are those that occurred prior to rescue medication. Five participants were excluded from analyses.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Sitagliptin	Phase A (Weeks 0-24): Sitagliptin 100 mg; Phase B (Weeks 24-54): Sitagliptin 100 mg + Placebo to Pioglitazone
Placebo/Pioglitazone	Phase A (Weeks 0-24): Placebo to Sitagliptin 100 mg; Phase B (Weeks 24-54): Placebo to Sitagliptin 100 mg + Pioglitazone 30 mg

Other Adverse Events

	Sitagliptin	**Placebo/Pioglitazone**
Total, other (not including serious) adverse events		
# participants affected / at risk	**49/210 (23.33%)**	**44/212 (20.75%)**

Infections and infestations		
Upper respiratory tract infection † 1		
# participants affected / at risk	**14/210 (6.67%)**	**15/212 (7.08%)**
# events	**15**	**16**
Metabolism and nutrition disorders		
Hypoglcaemia † 1		
# participants affected / at risk	**38/210 (18.10%)**	**31/212 (14.62%)**
# events	**187**	**148**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA 14.1

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. Any information identified by the sponsor as confidential must be deleted prior to submission. Sponsor review can be expedited to meet publication timelines.

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:

Moses RG, Round E, Shentu Y, Golm GT, O'neill EA, Gantz I, Engel SS, Kaufman KD, Goldstein BJ. A randomized clinical trial evaluating the safety and efficacy of sitagliptin added to the combination of sulfonylurea and metformin in patients with type 2 diabetes mellitus and inadequate glycemic control. J Diabetes. 2015 Dec 1. doi: 10.1111/1753-0407.12351. [Epub ahead of print]

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT01076075 History of Changes
Other Study ID Numbers:	0431-229 2010_513 MK-0431-229 (Other Identifier: protocol number)
Study First Received:	February 24, 2010
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Last Updated:	January 21, 2016
Health Authority:	Malaysia: Ministry of Health Australia: Department of Health and Ageing Therapeutic Goods Administration India: Ministry of Health

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