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Sitagliptin Versus Glipizide in Participants With Type 2 Diabetes Mellitus and Chronic Renal Insufficiency (MK-0431-063 AM1)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

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

ClinicalTrials.gov Identifier:
NCT00509262

First received: July 27, 2007
Last updated: April 27, 2015
Last verified: April 2015
History of Changes

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Purpose

The purpose of the study is to compare how sitagliptin and glipizide lower blood glucose levels in participants with moderate or severe renal insufficiency.

Condition	Intervention	Phase
Diabetes Mellitus, Type 2 Renal Insufficiency, Chronic	Drug: Sitagliptin Drug: Glipizide Drug: Placebo for Sitagliptin Drug: Placebo for Glipizide	Phase 3

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Safety/Efficacy Study
Intervention Model: Parallel Assignment
Masking: Double Blind (Subject, Investigator, Outcomes Assessor)
Primary Purpose: Treatment

Official Title: A Multicenter, Randomized, Double-Blind Study to Evaluate the Efficacy and Safety of Sitagliptin Versus Glipizide in Patients With Type 2 Diabetes Mellitus and Chronic Renal Insufficiency Who Have Inadequate Glycemic Control

Resource links provided by NLM:

MedlinePlus related topics: Chronic Kidney Disease Diabetes Type 2

Drug Information available for: Glipizide 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) Levels at Week 54 [Time Frame: Baseline to Week 54] [Designated as safety issue: No]

  A1C represents percentage of glycosylated hemoglobin.

- Percentage of Participants With Hypoglycemic Events [Time Frame: Baseline up to 28 days following the last dose of study therapy] [Designated as safety issue: Yes]

  Percentage of participants with at least one symptomatic hypoglycemic adverse event, excluding data after initiation of glycemic rescue therapy.

Secondary Outcome Measures:

- Change From Baseline in Fasting Plasma Glucose (FPG) at Week 54 [Time Frame: Baseline to Week 54] [Designated as safety issue: No]
- Change From Baseline in Body Weight at Week 54 [Time Frame: Baseline to Week 54] [Designated as safety issue: Yes]

Enrollment:	426
Study Start Date:	October 2007
Study Completion Date:	March 2011
Primary Completion Date:	March 2011 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: Sitagliptin Sitagliptin + Placebo for Glipizide	Drug: Sitagliptin Participants with moderate renal insufficiency will receive two sitagliptin 25 mg tablets orally daily; participants with severe renal insufficiency will receive one sitagliptin 25 mg tablet orally daily Other Names: • MK-0431 • Januvia Drug: Placebo for Glipizide Participants will receive 1/2 tablet of placebo for glipizide orally once daily up to 2 tablets orally twice daily
Active Comparator: Glipizide Glipizide + Placebo for Sitagliptin	Drug: Glipizide Participants will receive glipizide 2.5 mg (1/2 tablet) orally once daily up to 20 mg orally daily (10 mg twice daily) Other Name: Glucotrol Drug: Placebo for Sitagliptin Participants with moderate renal insufficiency will receive 2 placebo for sitagliptin tablets orally daily; participants with severe renal insufficiency will receive 1 placebo for sitagliptin tablet orally daily

Eligibility

Ages Eligible for Study:	30 Years and older
Genders Eligible for Study:	Both
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- Has type 2 diabetes mellitus
- Has moderate or severe renal insufficiency

Exclusion Criteria:

- Has type 1 diabetes mellitus or a history of ketoacidosis
- Is on a new weight loss program
- Has active liver disease
- Is on dialysis or is likely to need dialysis during the study

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:

Arjona Ferreira JC, Marre M, Barzilai N, Guo H, Golm GT, Sisk CM, Kaufman KD, Goldstein BJ. Efficacy and safety of sitagliptin versus glipizide in patients with type 2 diabetes and moderate-to-severe chronic renal insufficiency. Diabetes Care. 2013 May;36(5):1067-73. doi: 10.2337/dc12-1365. Epub 2012 Dec 17.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00509262 History of Changes
Other Study ID Numbers:	0431-063 2007_549
Study First Received:	July 27, 2007
Results First Received:	February 28, 2012
Last Updated:	April 27, 2015
Health Authority:	United States: Food and Drug Administration

Additional relevant MeSH terms:

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

ClinicalTrials.gov processed this record on April 13, 2016

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Results First Received: February 28, 2012

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Investigator, Outcomes Assessor); Primary Purpose: Treatment
Conditions:	Diabetes Mellitus, Type 2 Renal Insufficiency, Chronic
Interventions:	Drug: Sitagliptin Drug: Glipizide Drug: Placebo for Sitagliptin Drug: Placebo for Glipizide

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

One site was identified as non-compliant with some of the requirements of Good Clinical Practice. For this reason, data from the 3 participants randomized at this site were deemed unreliable and were removed from all analyses.

Reporting Groups

	Description
Sitagliptin	Participants randomized to 25 or 50 mg of sitagliptin orally daily + placebo for glipizide
Glipizide	Participants randomized to glipizide 2.5 to 20 mg orally daily + placebo for sitagliptin

Participant Flow: Overall Study

	Sitagliptin	Glipizide
STARTED	**211**	**212**
COMPLETED	**164**	**170**
NOT COMPLETED	**47**	**42**
Adverse Event	**16**	**18**
Not specified	**2**	**2**
Lack of Efficacy	**1**	**0**
Lost to Follow-up	**1**	**6**
Physician Decision	**1**	**3**
Protocol Violation	**2**	**2**
Withdrawal by Subject	**24**	**11**

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	Participants randomized to 25 or 50 mg of sitagliptin orally daily + placebo for glipizide
Glipizide	Participants randomized to glipizide 2.5 to 20 mg orally daily + placebo for sitagliptin
Total	Total of all reporting groups

Baseline Measures

	Sitagliptin	Glipizide	Total
Number of Participants [units: participants]	**211**	**212**	**423**

Age [units: years] Mean (Standard Deviation)	**64.2 (10.7)**	**64.2 (9.4)**	**64.2 (10.1)**
Gender [units: participants]			
Female	**80**	**90**	**170**
Male	**131**	**122**	**253**

Outcome Measures

Hide All Outcome Measures

1. Primary: Change From Baseline in Hemoglobin A1c (A1C) Levels at Week 54 [Time Frame: Baseline to Week 54]

Measure Type	Primary
Measure Title	Change From Baseline in Hemoglobin A1c (A1C) Levels at Week 54
Measure Description	A1C represents percentage of glycosylated hemoglobin.
Time Frame	Baseline to 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.
The per protocol population required that a participant had measurements both at baseline and at Week 54, and did not have any major protocol violations (e.g. drug compliance <75%, addition of prohibited antihyperglycemic agent, or incorrect double-blind study medication). No missing data were imputed.

Reporting Groups

	Description
Sitagliptin	Participants received 25 or 50 mg of sitagliptin orally daily + placebo for glipizide
Glipizide	Participants received glipizide 2.5 to 20 mg orally daily + placebo for sitagliptin

Measured Values

	Sitagliptin	**Glipizide**
Number of Participants Analyzed [units: participants]	**135**	**142**
Change From Baseline in Hemoglobin A1c (A1C) Levels at Week 54 [units: Percent of glycosylated hemoglobin] Mean (Standard Deviation)		
Baseline	**7.76 (0.65)**	**7.79 (0.70)**
Change from Baseline at Week 54	**-0.70 (0.80)**	**-0.62 (0.91)**

Statistical Analysis 1 for Change From Baseline in Hemoglobin A1c (A1C) Levels at Week 54

Groups [1]	All groups
Non-Inferiority/Equivalence Test [2]	Yes
Method [3]	ANCOVA
Difference in least squares mean [4]	-0.11
Standard Deviation	(0.74)
95% Confidence Interval	-0.29 to 0.06

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Details of power calculation, definition of non-inferiority margin, and other key parameters:
	The pre-specified non-inferiority margin was 0.4%; i.e., non-inferiority required that the upper boundary of the 95% confidence interval for the treatment difference (sitagliptin minus glipizide) to be less than 0.4%.
[3]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[4]	Other relevant estimation information:
	Based on analysis of covariance with terms for treatment, renal insufficiency stratum at Visit 4/Week -2 (moderate, or severe), prior diabetes pharmacotherapy (on or not on oral antihyperglycemic agent), and a covariate for baseline A1C.

2. Primary: Percentage of Participants With Hypoglycemic Events [Time Frame: Baseline up to 28 days following the last dose of study therapy]

Measure Type	Primary
Measure Title	Percentage of Participants With Hypoglycemic Events
Measure Description	Percentage of participants with at least one symptomatic hypoglycemic adverse event, excluding data after initiation of glycemic rescue therapy.
Time Frame	Baseline up to 28 days following the last dose of study therapy
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.
All participants as treated (APaT) population included all randomized participants who took at least one dose of study therapy.

Reporting Groups

	Description
Sitagliptin	Participants received 25 or 50 mg of sitagliptin orally daily + placebo for glipizide
Glipizide	Participants received glipizide 2.5 to 20 mg orally daily + placebo for sitagliptin

Measured Values

	Sitagliptin	**Glipizide**

Number of Participants Analyzed [units: participants]	**210**	**212**
Percentage of Participants With Hypoglycemic Events [units: percentage of participants]	**6.2**	**17.0**

Statistical Analysis 1 for Percentage of Participants With Hypoglycemic Events

Groups [1]	All groups
Method [2]	Miettirnen& Nurminen method
P Value [3]	0.001
Mean Difference (Final Values) [4]	-10.8
95% Confidence Interval	-17.1 to -4.8

[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:
	No text entered.
[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:
	Miettirnen & Nurminen method stratified by renal insufficiency stratum at Visit 4/Week -2 (moderate or severe) & prior diabetes pharmacotherapy

3. Secondary: Change From Baseline in Fasting Plasma Glucose (FPG) at Week 54 [Time Frame: Baseline to Week 54]

Measure Type	Secondary
Measure Title	Change From Baseline in Fasting Plasma Glucose (FPG) at Week 54
Measure Description	No text entered.
Time Frame	Baseline to 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.
The per protocol population required that a participant had measurements both at baseline and at Week 54, and did not have any major protocol violations (e.g. drug compliance <75%, addition of prohibited antihyperglycemic agent, or incorrect double-blind study medication). No missing data were imputed.

Reporting Groups

	Description

Sitagliptin	Participants received 25 or 50 mg of sitagliptin orally daily + placebo for glipizide
Glipizide	Participants received glipizide 2.5 to 20 mg orally daily + placebo for sitagliptin

Measured Values

	Sitagliptin	Glipizide
Number of Participants Analyzed [units: participants]	**136**	**142**
Change From Baseline in Fasting Plasma Glucose (FPG) at Week 54 **[units: mg/dL]** **Mean (Standard Deviation)**		
Baseline	**148.6 (39.9)**	**143.9 (35.7)**
Change from Baseline at Week 54	**-16.7 (47.1)**	**-20.2 (48.6)**

Statistical Analysis 1 for Change From Baseline in Fasting Plasma Glucose (FPG) at Week 54

Groups [1]	All groups
Method [2]	ANCOVA
Difference in least squares mean [3]	7.1
Standard Deviation	(38.3)
95% Confidence Interval	-1.9 to 16.1

[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:
	No text entered.
[3]	Other relevant estimation information:
	Analysis of covariance with terms for treatment, renal insufficiency stratum at Visit 4/Week -2 (moderate or severe), prior diabetes pharmacotherapy (on or not on oral antihyperglycemic agent), and a covariate for baseline Fasting Plasma Glucose.

4. Secondary: Change From Baseline in Body Weight at Week 54 [Time Frame: Baseline to Week 54]

Measure Type	Secondary
Measure Title	Change From Baseline in Body Weight at Week 54
Measure Description	No text entered.
Time Frame	Baseline 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.

All participants as treated (APaT) population included participants who had both baseline and Week 54 data (excluding data after initiation of glycemic rescue therapy).

Reporting Groups

	Description
Sitagliptin	Participants received 25 or 50 mg of sitagliptin orally daily + placebo for glipizide
Glipizide	Participants received glipizide 2.5 to 20 mg orally daily + placebo for sitagliptin

Measured Values

	Sitagliptin	Glipizide
Number of Participants Analyzed [units: participants]	**143**	**148**
Change From Baseline in Body Weight at Week 54 [units: kg] Least Squares Mean (Standard Error)	**-0.6 (0.3)**	**1.2 (0.3)**

Statistical Analysis 1 for Change From Baseline in Body Weight at Week 54

Groups [1]	All groups
Method [2]	ANCOVA
P Value [3]	<0.001
Difference in least squares mean [4]	-1.8
Standard Deviation	(3.8)
95% Confidence Interval	-2.6 to -1.0

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[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:
	Analysis of covariance with terms of treatment, renal insufficiency stratum at Visit 4/Week -2 (moderate or severe), prior diabetes pharmacotherapy (on or not on oral antihyperglycemic agent), and a covariate for baseline body weight.

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	No text entered.
Additional Description	One participant from the sitagliptin group did not receive any study medication and, therefore, was excluded from all analyses. Analyses of safety used the APaT population (participants who had both baseline and Week 54 data, and for serious adverse events only, included data after the initiation of glycemic rescue therapy).

Reporting Groups

	Description
Sitagliptin	Participants received 25 or 50 mg of sitagliptin orally daily + placebo for glipizide
Glipizide	Participants received glipizide 2.5 to 20 mg orally daily + placebo for sitagliptin

Serious Adverse Events

	Sitagliptin	Glipizide
Total, serious adverse events		
# participants affected / at risk	**36/210 (17.14%)**	**38/212 (17.92%)**
Blood and lymphatic system disorders		
Anaemia † 1		
# participants affected / at risk	**0/210 (0.00%)**	**1/212 (0.47%)**
# events	**0**	**1**
Cardiac disorders		
Acute coronary syndrome † 1		
# participants affected / at risk	**0/210 (0.00%)**	**1/212 (0.47%)**
# events	**0**	**1**
Acute myocardial infarction † 1		
# participants affected / at risk	**1/210 (0.48%)**	**2/212 (0.94%)**
# events	**1**	**2**
Angina pectoris † 1		
# participants affected / at risk	**0/210 (0.00%)**	**1/212 (0.47%)**
# events	**0**	**1**
Angina unstable † 1		
# participants affected / at risk	**0/210 (0.00%)**	**1/212 (0.47%)**
# events	**0**	**1**
Atrial fibrillation † 1		
# participants affected / at risk	**0/210 (0.00%)**	**1/212 (0.47%)**
# events	**0**	**1**
Cardiac failure † 1		
# participants affected / at risk	**0/210 (0.00%)**	**2/212 (0.94%)**
# events	**0**	**3**
Cardiac failure congestive † 1		
# participants affected / at risk	**0/210 (0.00%)**	**3/212 (1.42%)**
# events	**0**	**3**
Coronary artery disease † 1		
# participants affected / at risk	**1/210 (0.48%)**	**0/212 (0.00%)**
# events	**1**	**0**

Myocardial infarction † 1		
# participants affected / at risk	**2/210 (0.95%)**	**1/212 (0.47%)**
# events	**2**	**1**
Nodal arrhythmia † 1		
# participants affected / at risk	**0/210 (0.00%)**	**1/212 (0.47%)**
# events	**0**	**1**
Eye disorders		
Diabetic retinopathy † 1		
# participants affected / at risk	**1/210 (0.48%)**	**0/212 (0.00%)**
# events	**1**	**0**
Gastrointestinal disorders		
Abdominal pain † 1		
# participants affected / at risk	**0/210 (0.00%)**	**1/212 (0.47%)**
# events	**0**	**1**
Colitis † 1		
# participants affected / at risk	**1/210 (0.48%)**	**0/212 (0.00%)**
# events	**1**	**0**
Gastrooesophageal reflux disease † 1		
# participants affected / at risk	**0/210 (0.00%)**	**1/212 (0.47%)**
# events	**0**	**1**
Intestinal obstruction † 1		
# participants affected / at risk	**0/210 (0.00%)**	**1/212 (0.47%)**
# events	**0**	**1**
Uraemic gastropathy † 1		
# participants affected / at risk	**0/210 (0.00%)**	**1/212 (0.47%)**
# events	**0**	**1**
General disorders		
Asthenia † 1		
# participants affected / at risk	**0/210 (0.00%)**	**1/212 (0.47%)**
# events	**0**	**1**
Death † 1		
# participants affected / at risk	**1/210 (0.48%)**	**0/212 (0.00%)**
# events	**1**	**0**
Non-cardiac chest pain † 1		
# participants affected / at risk	**0/210 (0.00%)**	**1/212 (0.47%)**
# events	**0**	**1**
Sudden death † 1		
# participants affected / at risk	**1/210 (0.48%)**	**0/212 (0.00%)**
# events	**1**	**0**
Hepatobiliary disorders		
Cholecystitis acute † 1		
# participants affected / at risk	**1/210 (0.48%)**	**1/212 (0.47%)**
# events	**1**	**1**
Cholelithiasis † 1		

# participants affected / at risk	1/210 (0.48%)	0/212 (0.00%)
# events	1	0
Hepatic cirrhosis † 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
Gangrene † 1		
# participants affected / at risk	0/210 (0.00%)	1/212 (0.47%)
# events	0	1
Lobar pneumonia † 1		
# participants affected / at risk	0/210 (0.00%)	1/212 (0.47%)
# events	0	1
Localised infection † 1		
# participants affected / at risk	1/210 (0.48%)	0/212 (0.00%)
# events	1	0
Lung abscess † 1		
# participants affected / at risk	1/210 (0.48%)	0/212 (0.00%)
# events	1	0
Pneumonia † 1		
# participants affected / at risk	0/210 (0.00%)	1/212 (0.47%)
# events	0	1
Postoperative wound infection † 1		
# participants affected / at risk	0/210 (0.00%)	1/212 (0.47%)
# events	0	1
Sepsis † 1		
# participants affected / at risk	0/210 (0.00%)	1/212 (0.47%)
# events	0	1
Urinary tract infection † 1		
# participants affected / at risk	3/210 (1.43%)	1/212 (0.47%)
# events	3	1
Urosepsis † 1		
# participants affected / at risk	0/210 (0.00%)	1/212 (0.47%)
# events	0	1
Viral infection † 1		
# participants affected / at risk	0/210 (0.00%)	1/212 (0.47%)
# events	0	1
Injury, poisoning and procedural complications		
Arteriovenous fistula thrombosis † 1		
# participants affected / at risk	1/210 (0.48%)	0/212 (0.00%)
# events	2	0
Femur fracture † 1		
# participants affected / at risk	0/210 (0.00%)	1/212 (0.47%)

# events	0	1
Joint dislocation † 1		
# participants affected / at risk	1/210 (0.48%)	0/212 (0.00%)
# events	1	0
Patella fracture † 1		
# participants affected / at risk	1/210 (0.48%)	0/212 (0.00%)
# events	1	0
Tendon rupture † 1		
# participants affected / at risk	1/210 (0.48%)	0/212 (0.00%)
# events	1	0
Vascular graft thrombosis † 1		
# participants affected / at risk	1/210 (0.48%)	0/212 (0.00%)
# events	1	0
Metabolism and nutrition disorders		
Dehydration † 1		
# participants affected / at risk	1/210 (0.48%)	0/212 (0.00%)
# events	1	0
Diabetic ketoacidosis † 1		
# participants affected / at risk	1/210 (0.48%)	0/212 (0.00%)
# events	1	0
Hyperglycaemia † 1		
# participants affected / at risk	0/210 (0.00%)	1/212 (0.47%)
# events	0	1
Hyperkalaemia † 1		
# participants affected / at risk	1/210 (0.48%)	0/212 (0.00%)
# events	1	0
Hypoglycaemia † 1		
# participants affected / at risk	1/210 (0.48%)	4/212 (1.89%)
# events	1	5
Hyponatraemia † 1		
# participants affected / at risk	0/210 (0.00%)	1/212 (0.47%)
# events	0	1
Musculoskeletal and connective tissue disorders		
Costochondritis † 1		
# participants affected / at risk	1/210 (0.48%)	0/212 (0.00%)
# events	1	0
Musculoskeletal chest pain † 1		
# participants affected / at risk	1/210 (0.48%)	0/212 (0.00%)
# events	1	0
Osteoarthritis † 1		
# participants affected / at risk	1/210 (0.48%)	0/212 (0.00%)
# events	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Breast cancer † 1		

# participants affected / at risk	1/210 (0.48%)	0/212 (0.00%)
# events	1	0
Chronic myeloid leukaemia † 1		
# participants affected / at risk	1/210 (0.48%)	0/212 (0.00%)
# events	1	0
Lung squamous cell carcinoma stage unspecified † 1		
# participants affected / at risk	1/210 (0.48%)	0/212 (0.00%)
# events	1	0
Pancreatic carcinoma † 1		
# participants affected / at risk	1/210 (0.48%)	0/212 (0.00%)
# events	1	0
Nervous system disorders		
Cerebrovascular accident † 1		
# participants affected / at risk	2/210 (0.95%)	1/212 (0.47%)
# events	2	1
Guillain-Barre syndrome † 1		
# participants affected / at risk	1/210 (0.48%)	0/212 (0.00%)
# events	1	0
Haemorrhagic stroke † 1		
# participants affected / at risk	0/210 (0.00%)	1/212 (0.47%)
# events	0	1
Subarachnoid haemorrhage † 1		
# participants affected / at risk	1/210 (0.48%)	0/212 (0.00%)
# events	1	0
Transient ischaemic attack † 1		
# participants affected / at risk	1/210 (0.48%)	1/212 (0.47%)
# events	1	1
Psychiatric disorders		
Acute psychosis † 1		
# participants affected / at risk	1/210 (0.48%)	0/212 (0.00%)
# events	1	0
Depression † 1		
# participants affected / at risk	0/210 (0.00%)	1/212 (0.47%)
# events	0	1
Renal and urinary disorders		
Azotaemia † 1		
# participants affected / at risk	1/210 (0.48%)	1/212 (0.47%)
# events	1	1
Calculus ureteric † 1		
# participants affected / at risk	0/210 (0.00%)	1/212 (0.47%)
# events	0	1
Nephropathy † 1		
# participants affected / at risk	0/210 (0.00%)	1/212 (0.47%)
# events	0	1
Renal failure acute † 1		

# participants affected / at risk	1/210 (0.48%)	2/212 (0.94%)
# events	1	3
Renal failure chronic † 1		
# participants affected / at risk	1/210 (0.48%)	2/212 (0.94%)
# events	1	3
Reproductive system and breast disorders		
Benign prostatic hyperplasia † 1		
# participants affected / at risk	2/210 (0.95%)	0/212 (0.00%)
# events	2	0
Respiratory, thoracic and mediastinal disorders		
Asthmatic crisis † 1		
# participants affected / at risk	1/210 (0.48%)	0/212 (0.00%)
# events	1	0
Chronic obstructive pulmonary disease † 1		
# participants affected / at risk	0/210 (0.00%)	1/212 (0.47%)
# events	0	1
Pneumothorax † 1		
# participants affected / at risk	0/210 (0.00%)	1/212 (0.47%)
# events	0	1
Sleep apnoea syndrome † 1		
# participants affected / at risk	0/210 (0.00%)	1/212 (0.47%)
# events	0	1
Skin and subcutaneous tissue disorders		
Psoriasis † 1		
# participants affected / at risk	1/210 (0.48%)	0/212 (0.00%)
# events	1	0
Vascular disorders		
Haematoma † 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 13.1

Other Adverse Events

Hide Other Adverse Events

Time Frame	No text entered.
Additional Description	One participant from the sitagliptin group did not receive any study medication and, therefore, was excluded from all analyses. Analyses of safety used the APaT population (participants who had both baseline and Week 54 data, and for serious adverse events only, included data after the initiation of glycemic rescue therapy).

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Sitagliptin	Participants received 25 or 50 mg of sitagliptin orally daily + placebo for glipizide
Glipizide	Participants received glipizide 2.5 to 20 mg orally daily + placebo for sitagliptin

Other Adverse Events

	Sitagliptin	Glipizide
Total, other (not including serious) adverse events		
# participants affected / at risk	**69/210 (32.86%)**	**89/212 (41.98%)**
Gastrointestinal disorders		
Diarrhoea † 1		
# participants affected / at risk	**11/210 (5.24%)**	**12/212 (5.66%)**
# events	**14**	**13**
General disorders		
Oedema peripheral † 1		
# participants affected / at risk	**15/210 (7.14%)**	**10/212 (4.72%)**
# events	**17**	**11**
Infections and infestations		
Upper respiratory tract infection † 1		
# participants affected / at risk	**10/210 (4.76%)**	**15/212 (7.08%)**
# events	**15**	**19**
Urinary tract infection † 1		
# participants affected / at risk	**11/210 (5.24%)**	**20/212 (9.43%)**
# events	**13**	**31**
Investigations		
Blood glucose decreased † 1		
# participants affected / at risk	**15/210 (7.14%)**	**32/212 (15.09%)**
# events	**29**	**159**
Metabolism and nutrition disorders		
Hypoglycaemia † 1		
# participants affected / at risk	**12/210 (5.71%)**	**35/212 (16.51%)**
# events	**21**	**89**
Nervous system disorders		
Dizziness † 1		
# participants affected / at risk	**7/210 (3.33%)**	**11/212 (5.19%)**
# events	**7**	**12**
Vascular disorders		
Hypertension † 1		
# participants affected / at risk	**11/210 (5.24%)**	**6/212 (2.83%)**
# events	**11**	**6**

† 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. Any information identified by the Sponsor as confidential must be deleted prior to submission.

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:

Arjona Ferreira JC, Marre M, Barzilai N, Guo H, Golm GT, Sisk CM, Kaufman KD, Goldstein BJ. Efficacy and safety of sitagliptin versus glipizide in patients with type 2 diabetes and moderate-to-severe chronic renal insufficiency. Diabetes Care. 2013 May;36(5):1067-73. doi: 10.2337/dc12-1365. Epub 2012 Dec 17.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00509262 History of Changes
Other Study ID Numbers:	0431-063 2007_549 (Other Identifier: Merck Registration Number)
Study First Received:	July 27, 2007
Results First Received:	February 28, 2012
Last Updated:	April 27, 2015

Health Authority: United States: Food and Drug Administration

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