An Investigational Drug in Patients With Type 2 Diabetes Mellitus and Chronic Renal Insufficiency (0431-028)(COMPLETED)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

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

ClinicalTrials.gov Identifier:
NCT00095056

First received: October 29, 2004
Last updated: March 12, 2015
Last verified: March 2015
History of Changes

Purpose

The purpose of this study is to determine the safety and tolerability of an investigational drug in patients with Type 2 Diabetes Mellitus (a specific type of diabetes) and Chronic Renal Insufficiency (inadequate kidney function).

Condition	Intervention	Phase
Diabetes Mellitus, Type 2 Chronic Renal Insufficiency	Drug: sitagliptin Drug: Placebo to Sitagliptin Drug: glipizide Drug: Placebo to glipizide	Phase 3

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

Official Title: Sitagliptin Study in Patients With Type 2 Diabetes Mellitus and Chronic Renal Insufficiency

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:

- Safety and Tolerability of Sitagliptin After 12 Weeks of Treatment [Time Frame: Week 0 through Week 12] [Designated as safety issue: Yes]

  Safety and tolerability were measured in terms of the number of patients with clinical adverse experiences (CAEs), serious CAEs, drug-related CAEs, laboratory adverse experiences (LAEs), serious LAEs, and drug-related LAEs. Drug-relationship was assessed by the study investigator according to his/her best clinical judgment.

Secondary Outcome Measures:

- Safety and Tolerability of Sitagliptin Over 54 Weeks [Time Frame: Week 0 through Week 54] [Designated as safety issue: Yes]

  Safety and tolerability were measured in terms of the number of patients with clinical adverse experiences (CAEs), serious CAEs, drug-related CAEs, laboratory adverse experiences (LAEs), serious LAEs, and drug-related LAEs. Drug-relationship was assessed by the study investigator according to his/her best clinical judgment.

Enrollment:	91
Study Start Date:	October 2004
Study Completion Date:	July 2006
Primary Completion Date:	July 2006 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: Sitagliptin Participants in the Sitagliptin treatment sequence will receive sitagliptin in Phase A and placebo to glipizide in Phase B.	Drug: sitagliptin One (participants with visit 1 estimated creatinine clearance <30 mL/min or undergo regular dialysis) or Two (participants with visit 1 creatinine clearance of =30 to <50 mL/min; not on dialysis) tablets of 25 mg Sitagliptin daily. Other Name: MK0431 Drug: glipizide One 5 mg glipizide tablet per day. The dose of glipizide administered per day may be increased after 2 weeks and at 2-week intervals thereafter up to 20 mg based upon fingerstick glucose determinations. Drug: Placebo to glipizide One placebo to glipizide 5 mg tablet per day. The dose of placebo to glipizide administered per day may be increased after 2 weeks and at 2-week intervals thereafter up to 20 mg based upon fingerstick glucose determinations.
Placebo Comparator: Placebo Participants in the Placebo treatment sequence will receive placebo to sitagliptin in Phase A and glipizide in Phase B.	Drug: Placebo to Sitagliptin One (participants with visit 1 estimated creatinine clearance <30 mL/min or undergo regular dialysis) or Two (participants with visit 1 creatinine clearance of =30 to <50 mL/min and not on dialysis) tablets of placebo to sitagliptin 25 mg daily. Drug: glipizide One 5 mg glipizide tablet per day. The dose of glipizide administered per day may be increased after 2 weeks and at 2-week intervals thereafter up to 20 mg based upon fingerstick glucose determinations.

Eligibility

Ages Eligible for Study:	18 Years and older
Genders Eligible for Study:	Both
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- Patients who are at least 18 years of age diagnosed with type 2 diabetes mellitus (T2DM) (a specific type of diabetes).
- Patient has renal (kidney) insufficiency (inadequate kidney function)

Exclusion Criteria:

- Patient has had heart problems (such as a heart attack or chest pain) or stroke within the past 6 months or any condition or therapy which, in

the opinion of the investigator, may not be in the patient's best interest to participate.

- Pregnant or breast feeding

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: NCT00095056

Sponsors and Collaborators

Merck Sharp & Dohme Corp.

Investigators

Study Director: Medical Monitor Merck Sharp & Dohme Corp.

More Information

Publications:

Chan JC, Scott R, Arjona Ferreira JC, Sheng D, Gonzalez E, Davies MJ, Stein PP, Kaufman KD, Amatruda JM, Williams-Herman D. Safety and efficacy of sitagliptin in patients with type 2 diabetes and chronic renal insufficiency. Diabetes Obes Metab. 2008 Jul;10(7):545-55. doi: 10.1111/j.1463-1326.2008.00914.x. Epub 2008 Jun 1.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00095056 History of Changes
Other Study ID Numbers:	0431-028 2004_054
Study First Received:	October 29, 2004
Results First Received:	June 22, 2010
Last Updated:	March 12, 2015
Health Authority:	United States: Food and Drug Administration

Keywords provided by Merck Sharp & Dohme Corp.:
Type 2 Diabetes Mellitus and Chronic Renal Insufficiency

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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First received: October 29, 2004
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Results First Received: June 22, 2010

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

First Patient In: 14-Dec-04

Last Patient Last Visit: 27-Jul-06

75 study centers worldwide

Pre-Assignment Details

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

Patients ≥18 years of age with chronic renal insufficiency and type 2 diabetes mellitus who had an A1C of 6.5-10% (not on baseline insulin therapy) or 7.5-10% (on baseline insulin therapy) after an antihyperglycemic agent (AHA) wash-off period of up to 12 weeks, were eligible to enter the 54-week

study.

Reporting Groups

	Description
Sitagliptin	The Sitagliptin group includes data from patients randomized to receive treatment with either one (1) 25 mg oral tablet of sitagliptin once daily (blinded) [patients with Creatinine Clearance (CrCl) <30 mL/min or dialysis] or two (2) 25 mg oral tablets of sitagliptin once daily (blinded) [patients with CrCl 30 to <50mL/min] alone or in combination with baseline insulin therapy. During Phase B, patients in the Sitagliptin group (with the exception of patients on baseline insulin therapy and patients who received glycemic rescue medication in Phase A) were given glipizide placebo (blinded). During Phase B, patients on baseline insulin could have their insulin uptitrated, and patients who received glycemic rescue medication in Phase A continued on open-label rescue medication.
Placebo	The Placebo group includes data from patients randomized to receive treatment with either one (1) tablet of placebo matching sitagliptin 25 mg (blinded) [patients with CrCl <30 mL/min or dialysis] or two (2) tablets of placebo matching sitagliptin 25 mg (blinded) [patients with CrCl 30 to <50mL/min] alone or in combination with baseline insulin therapy. During Phase B, patients in the Placebo group (with the exception of patients on baseline insulin therapy and patients who received glycemic rescue medication in Phase A) were given glipizide (blinded). During Phase B, patients on baseline insulin could have their insulin uptitrated, and patients who received glycemic rescue medication in Phase A continued on open-label rescue medication.

Participant Flow for 2 periods

Period 1: Phase A (Weeks 0-12)

	Sitagliptin	Placebo
STARTED	65	26
COMPLETED	58	25
NOT COMPLETED	7	1
Adverse Event	1	1
Withdrawal by Subject	3	0
Death	1	0
Protocol specific criteria	2	0

Period 2: Phase B (Weeks 12-54)

	Sitagliptin	Placebo
STARTED	56 [1]	25
COMPLETED	46	20
NOT COMPLETED	10	5
Adverse Event	2	2
Lost to Follow-up	1	0

Withdrawal by Subject	**2**	**1**
Patient Moved	**1**	**0**
Death	**3**	**1**
Protocol specific criteria	**1**	**0**
Protocol Violation	**0**	**1**

[1] 2 randomized patients completed Period 1 but did not enter Period 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	The Sitagliptin group includes data from patients randomized to receive treatment with either one (1) 25 mg oral tablet of sitagliptin once daily (blinded) [patients with Creatinine Clearance (CrCl) <30 mL/min or dialysis] or two (2) 25 mg oral tablets of sitagliptin once daily (blinded) [patients with CrCl 30 to <50mL/min] alone or in combination with baseline insulin therapy. During Phase B, patients in the Sitagliptin group (with the exception of patients on baseline insulin therapy and patients who received glycemic rescue medication in Phase A) were given glipizide placebo (blinded). During Phase B, patients on baseline insulin could have their insulin uptitrated, and patients who received glycemic rescue medication in Phase A continued on open-label rescue medication.
Placebo	The Placebo group includes data from patients randomized to receive treatment with either one (1) tablet of placebo matching sitagliptin 25 mg (blinded) [patients with CrCl <30 mL/min or dialysis] or two (2) tablets of placebo matching sitagliptin 25 mg (blinded) [patients with CrCl 30 to <50mL/min] alone or in combination with baseline insulin therapy. During Phase B, patients in the Placebo group (with the exception of patients on baseline insulin therapy and patients who received glycemic rescue medication in Phase A) were given glipizide (blinded). During Phase B, patients on baseline insulin could have their insulin uptitrated, and patients who received glycemic rescue medication in Phase A continued on open-label rescue medication.
Total	Total of all reporting groups

Baseline Measures

	Sitagliptin	**Placebo**	**Total**
Number of Participants [units: participants]	**65**	**26**	**91**
Age [units: years] Mean (Standard Deviation)	**68.9 (9.8)**	**65.3 (9.7)**	**67.9 (9.8)**
Gender [units: participants]			
Female	**34**	**10**	**44**
Male	**31**	**16**	**47**

Race/Ethnicity, Customized [units: participants]			
White	**22**	**8**	**30**
Black	**4**	**1**	**5**
Hispanic	**17**	**9**	**26**
Asian	**20**	**7**	**27**
Other	**2**	**1**	**3**
HbA1c (Hemoglobin A1c) [units: Percent] Mean (Standard Deviation)	**7.6 (0.9)**	**7.8 (0.9)**	**7.7 (0.9)**

Outcome Measures

Hide All Outcome Measures

1. Primary: Safety and Tolerability of Sitagliptin After 12 Weeks of Treatment [Time Frame: Week 0 through Week 12]

Measure Type	Primary
Measure Title	Safety and Tolerability of Sitagliptin After 12 Weeks of Treatment
Measure Description	Safety and tolerability were measured in terms of the number of patients with clinical adverse experiences (CAEs), serious CAEs, drug-related CAEs, laboratory adverse experiences (LAEs), serious LAEs, and drug-related LAEs. Drug-relationship was assessed by the study investigator according to his/her best clinical judgment.
Time Frame	Week 0 through Week 12
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 patients who took study medication were included in the analysis. Events that occurred after initiation of glycemic rescue therapy were excluded from the analysis of CAEs, drug-related CAEs, LAEs, & drug-related LAEs. Events that occurred after initiation of glycemic rescue therapy were included in the analysis of serious CAEs and serious LAEs.

Reporting Groups

	Description
Sitagliptin	The Sitagliptin group includes data from patients randomized to receive treatment with either one (1) 25 mg oral tablet of sitagliptin once daily (blinded) [patients with Creatinine Clearance (CrCl) <30 mL/min or dialysis] or two (2) 25 mg oral tablets of sitagliptin once daily (blinded) [patients with CrCl 30 to <50mL/min] alone or in combination with baseline insulin therapy. During Phase B, patients in the Sitagliptin group (with the exception of patients on baseline insulin therapy and patients who received glycemic rescue medication in Phase A) were given glipizide placebo (blinded). During Phase B, patients on baseline insulin could have their insulin uptitrated, and patients who received glycemic rescue medication in Phase A continued on open-label rescue medication.
Placebo	The Placebo group includes data from patients randomized to receive treatment with either one (1) tablet of placebo matching sitagliptin 25 mg (blinded) [patients with CrCl <30 mL/min or dialysis] or two (2) tablets of placebo matching sitagliptin 25 mg (blinded) [patients with CrCl 30 to <50mL/min] alone or in combination with baseline insulin therapy. During Phase B, patients in the Placebo group (with the exception of patients on baseline insulin therapy and patients who received glycemic rescue medication in Phase A) were given glipizide (blinded). During Phase B, patients on baseline insulin could have their insulin uptitrated, and patients who received glycemic rescue medication in Phase A continued on open-label rescue medication.

Measured Values

	Sitagliptin	Placebo
Number of Participants Analyzed [units: participants]	**65**	**26**
Safety and Tolerability of Sitagliptin After 12 Weeks of Treatment [units: Participants]		
With CAEs	**41**	**16**
With drug-related CAEs	**8**	**1**
With serious CAEs	**9**	**1**
With LAEs	**9**	**5**
With drug-related LAEs	**1**	**0**
With serious LAEs	**0**	**0**

No statistical analysis provided for Safety and Tolerability of Sitagliptin After 12 Weeks of Treatment

2. Secondary: Safety and Tolerability of Sitagliptin Over 54 Weeks [Time Frame: Week 0 through Week 54]

Measure Type	Secondary
Measure Title	Safety and Tolerability of Sitagliptin Over 54 Weeks
Measure Description	Safety and tolerability were measured in terms of the number of patients with clinical adverse experiences (CAEs), serious CAEs, drug-related CAEs, laboratory adverse experiences (LAEs), serious LAEs, and drug-related LAEs. Drug-relationship was assessed by the study investigator according to his/her best clinical judgment.
Time Frame	Week 0 through 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 patients who took study medication were included in the analysis. Events that occurred after initiation of glycemic rescue therapy were excluded from the analysis of CAEs, drug-related CAEs, LAEs, & drug-related LAEs. Events that occurred after initiation of glycemic rescue therapy were included in the analysis of serious CAEs and serious LAEs.

Reporting Groups

	Description
Sitagliptin	The Sitagliptin group includes data from patients randomized to receive treatment with either one (1) 25 mg oral tablet of sitagliptin once daily (blinded) [patients with Creatinine Clearance (CrCl) <30 mL/min or dialysis] or two (2) 25 mg oral tablets of sitagliptin once daily (blinded) [patients with CrCl 30 to <50mL/min] alone or in combination with baseline insulin therapy. During Phase B, patients in the Sitagliptin group (with the exception of patients on baseline insulin therapy and patients who received glycemic rescue medication in Phase A) were given glipizide placebo (blinded). During Phase B, patients on baseline insulin could have their insulin uptitrated, and patients who received glycemic rescue medication in Phase A continued on open-label rescue medication.
Placebo	The Placebo group includes data from patients randomized to receive treatment with either one (1) tablet of placebo matching sitagliptin 25 mg (blinded) [patients with CrCl <30 mL/min or dialysis] or two (2) tablets of placebo matching sitagliptin 25 mg (blinded) [patients with CrCl 30 to <50mL/min] alone or in combination with baseline insulin therapy. During Phase B, patients in

	the Placebo group (with the exception of patients on baseline insulin therapy and patients who received glycemic rescue medication in Phase A) were given glipizide (blinded). During Phase B, patients on baseline insulin could have their insulin uptitrated, and patients who received glycemic rescue medication in Phase A continued on open-label rescue medication.

Measured Values

	Sitagliptin	Placebo
Number of Participants Analyzed [units: participants]	**65**	**26**
Safety and Tolerability of Sitagliptin Over 54 Weeks [units: Participants]		
With CAEs	**50**	**22**
With drug-related CAEs	**8**	**5**
With serious CAEs	**20**	**10**
With LAEs	**15**	**8**
With drug-related LAEs	**2**	**0**
With serious LAEs	**0**	**0**

No statistical analysis provided for Safety and Tolerability of Sitagliptin Over 54 Weeks

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	Week 0 through Week 54
Additional Description	Patients received rescue medication if they met specific glycemic goals. This summary of SAEs includes events that occurred either before or after receiving rescue medication. This summary of Other AEs includes only those AEs that occurred prior to a patient receiving rescue medication.

Reporting Groups

	Description
Sitagliptin	The Sitagliptin group includes data from patients randomized to receive treatment with either one (1) 25 mg oral tablet of sitagliptin once daily (blinded) [patients with Creatinine Clearance (CrCl) <30 mL/min or dialysis] or two (2) 25 mg oral tablets of sitagliptin once daily (blinded) [patients with CrCl 30 to <50mL/min] alone or in combination with baseline insulin therapy. During Phase B, patients in the Sitagliptin group (with the exception of patients on baseline insulin therapy and patients who received glycemic rescue medication in Phase A) were given glipizide placebo (blinded). During Phase B, patients on baseline insulin could have their insulin uptitrated, and patients who received glycemic rescue medication in Phase A continued on open-label rescue medication.
Placebo	The Placebo group includes data from patients randomized to receive treatment with either one (1) tablet of placebo matching sitagliptin 25 mg (blinded) [patients with CrCl <30 mL/min or dialysis] or two (2) tablets of placebo matching sitagliptin 25 mg (blinded) [patients with CrCl 30 to <50mL/min] alone or in combination with baseline insulin therapy. During Phase B, patients in the Placebo group (with the exception of patients on baseline insulin therapy and patients who received glycemic rescue medication in Phase A) were given glipizide (blinded). During Phase B, patients on baseline insulin could have their insulin uptitrated, and patients who received glycemic rescue medication in Phase A continued on open-label rescue medication.

Serious Adverse Events

	Sitagliptin	Placebo

Total, serious adverse events		
# participants affected / at risk	**20/65 (30.77%)**	**10/26 (38.46%)**
Blood and lymphatic system disorders		
Anaemia [*1]		
# participants affected / at risk	**0/65 (0.00%)**	**2/26 (7.69%)**
Cardiac disorders		
Acute Myocardial Infarction [*1]		
# participants affected / at risk	**2/65 (3.08%)**	**0/26 (0.00%)**
Cardiac Failure [*1]		
# participants affected / at risk	**2/65 (3.08%)**	**0/26 (0.00%)**
Cardiac Failure Congestive [*1]		
# participants affected / at risk	**2/65 (3.08%)**	**0/26 (0.00%)**
Coronary Artery Stenosis [*1]		
# participants affected / at risk	**0/65 (0.00%)**	**1/26 (3.85%)**
Myocardial Infarction [*1]		
# participants affected / at risk	**1/65 (1.54%)**	**0/26 (0.00%)**
Myocardial Ischaemia [*1]		
# participants affected / at risk	**1/65 (1.54%)**	**0/26 (0.00%)**
Pericarditis [*1]		
# participants affected / at risk	**0/65 (0.00%)**	**1/26 (3.85%)**
Supraventricular Tachycardia [*1]		
# participants affected / at risk	**1/65 (1.54%)**	**0/26 (0.00%)**
Eye disorders		
Retinopathy [*1]		
# participants affected / at risk	**0/65 (0.00%)**	**1/26 (3.85%)**
Gastrointestinal disorders		
Abdominal Pain Upper [*1]		
# participants affected / at risk	**0/65 (0.00%)**	**1/26 (3.85%)**
Gastroduodenitis [*1]		
# participants affected / at risk	**1/65 (1.54%)**	**0/26 (0.00%)**
Large Intestinal Haemorrhage [*1]		
# participants affected / at risk	**0/65 (0.00%)**	**1/26 (3.85%)**
General disorders		
Death [*1]		
# participants affected / at risk	**1/65 (1.54%)**	**0/26 (0.00%)**
Sudden Death [*1]		
# participants affected / at risk	**1/65 (1.54%)**	**0/26 (0.00%)**
Infections and infestations		
Arteriovenous Graft Site Infection [*1]		
# participants affected / at risk	**0/65 (0.00%)**	**1/26 (3.85%)**

Bacteraemia [*1]		
# participants affected / at risk	**0/65 (0.00%)**	**1/26 (3.85%)**
Bronchitis [*1]		
# participants affected / at risk	**1/65 (1.54%)**	**0/26 (0.00%)**
Cellulitis [*1]		
# participants affected / at risk	**1/65 (1.54%)**	**0/26 (0.00%)**
Gastroenteritis [*1]		
# participants affected / at risk	**3/65 (4.62%)**	**0/26 (0.00%)**
Pneumonia [*1]		
# participants affected / at risk	**2/65 (3.08%)**	**0/26 (0.00%)**
Septic Shock [*1]		
# participants affected / at risk	**0/65 (0.00%)**	**1/26 (3.85%)**
Staphylococcal Infection [*1]		
# participants affected / at risk	**0/65 (0.00%)**	**2/26 (7.69%)**
Urinary Tract Infection [*1]		
# participants affected / at risk	**1/65 (1.54%)**	**1/26 (3.85%)**
Injury, poisoning and procedural complications		
Arteriovenous Fistula Thrombosis [*1]		
# participants affected / at risk	**0/65 (0.00%)**	**1/26 (3.85%)**
Polytraumatism [*1]		
# participants affected / at risk	**0/65 (0.00%)**	**1/26 (3.85%)**
Metabolism and nutrition disorders		
Diabetic Foot [*1]		
# participants affected / at risk	**0/65 (0.00%)**	**1/26 (3.85%)**
Hyperglycaemia [*1]		
# participants affected / at risk	**1/65 (1.54%)**	**0/26 (0.00%)**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Colon Cancer [*1]		
# participants affected / at risk	**0/65 (0.00%)**	**1/26 (3.85%)**
Metastases To Liver [*1]		
# participants affected / at risk	**1/65 (1.54%)**	**0/26 (0.00%)**
Pancreatic Carcinoma [*1]		
# participants affected / at risk	**1/65 (1.54%)**	**0/26 (0.00%)**
Prostate Cancer [*1]		
# participants affected / at risk	**0/65 (0.00%)**	**1/26 (3.85%)**
Squamous Cell Carcinoma Of Skin [*1]		
# participants affected / at risk	**2/65 (3.08%)**	**0/26 (0.00%)**
Nervous system disorders		
Cerebrovascular Accident [*1]		
# participants affected / at risk	**1/65 (1.54%)**	**0/26 (0.00%)**

Loss Of Consciousness * 1		
# participants affected / at risk	**1/65 (1.54%)**	**0/26 (0.00%)**
Thalamic Infarction * 1		
# participants affected / at risk	**0/65 (0.00%)**	**1/26 (3.85%)**
Transient Ischaemic Attack * 1		
# participants affected / at risk	**1/65 (1.54%)**	**0/26 (0.00%)**
Renal and urinary disorders		
Hydronephrosis * 1		
# participants affected / at risk	**1/65 (1.54%)**	**0/26 (0.00%)**
Renal Artery Stenosis * 1		
# participants affected / at risk	**0/65 (0.00%)**	**1/26 (3.85%)**
Renal Failure Chronic * 1		
# participants affected / at risk	**1/65 (1.54%)**	**0/26 (0.00%)**
Respiratory, thoracic and mediastinal disorders		
Acute Pulmonary Oedema * 1		
# participants affected / at risk	**1/65 (1.54%)**	**0/26 (0.00%)**
Vascular disorders		
Hypertension * 1		
# participants affected / at risk	**0/65 (0.00%)**	**2/26 (7.69%)**
Hypertensive Crisis * 1		
# participants affected / at risk	**1/65 (1.54%)**	**0/26 (0.00%)**

* Events were collected by non-systematic assessment

1 Term from vocabulary, MedDRA (9.0)

Other Adverse Events

Hide Other Adverse Events

Time Frame	Week 0 through Week 54
Additional Description	Patients received rescue medication if they met specific glycemic goals. This summary of SAEs includes events that occurred either before or after receiving rescue medication. This summary of Other AEs includes only those AEs that occurred prior to a patient receiving rescue medication.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Sitagliptin	The Sitagliptin group includes data from patients randomized to receive treatment with either one (1) 25 mg oral tablet of sitagliptin once daily (blinded) [patients with Creatinine Clearance (CrCl) <30 mL/min or dialysis] or two (2) 25 mg oral tablets of sitagliptin once daily (blinded) [patients with CrCl 30 to <50mL/min] alone or in combination with baseline insulin therapy. During Phase B, patients in the Sitagliptin group (with the exception of patients on baseline insulin therapy and patients who received glycemic rescue medication in Phase A) were given glipizide placebo (blinded). During Phase B, patients on baseline insulin could have their insulin uptitrated, and patients who received glycemic rescue medication in Phase A continued on open-label rescue

	medication.
Placebo	The Placebo group includes data from patients randomized to receive treatment with either one (1) tablet of placebo matching sitagliptin 25 mg (blinded) [patients with CrCl <30 mL/min or dialysis] or two (2) tablets of placebo matching sitagliptin 25 mg (blinded) [patients with CrCl 30 to <50mL/min] alone or in combination with baseline insulin therapy. During Phase B, patients in the Placebo group (with the exception of patients on baseline insulin therapy and patients who received glycemic rescue medication in Phase A) were given glipizide (blinded). During Phase B, patients on baseline insulin could have their insulin uptitrated, and patients who received glycemic rescue medication in Phase A continued on open-label rescue medication.

Other Adverse Events

	Sitagliptin	Placebo
Total, other (not including serious) adverse events		
# participants affected / at risk	**29/65 (44.62%)**	**20/26 (76.92%)**
Blood and lymphatic system disorders		
Anaemia [*1]		
# participants affected / at risk	**2/65 (3.08%)**	**2/26 (7.69%)**
Gastrointestinal disorders		
Constipation [*1]		
# participants affected / at risk	**1/65 (1.54%)**	**2/26 (7.69%)**
Diarrhoea [*1]		
# participants affected / at risk	**6/65 (9.23%)**	**4/26 (15.38%)**
Gastrooesophageal Reflux Disease [*1]		
# participants affected / at risk	**1/65 (1.54%)**	**2/26 (7.69%)**
General disorders		
Oedema Peripheral [*1]		
# participants affected / at risk	**2/65 (3.08%)**	**2/26 (7.69%)**
Infections and infestations		
Catheter Site Infection [*1]		
# participants affected / at risk	**0/65 (0.00%)**	**2/26 (7.69%)**
Nasopharyngitis [*1]		
# participants affected / at risk	**4/65 (6.15%)**	**1/26 (3.85%)**
Upper Respiratory Tract Infection [*1]		
# participants affected / at risk	**5/65 (7.69%)**	**5/26 (19.23%)**
Urinary Tract Infection [*1]		
# participants affected / at risk	**5/65 (7.69%)**	**3/26 (11.54%)**
Investigations		
Blood Creatinine Increased [*1]		
# participants affected / at risk	**1/65 (1.54%)**	**2/26 (7.69%)**
Blood Glucose Increased [*1]		
# participants affected / at risk	**3/65 (4.62%)**	**3/26 (11.54%)**
Metabolism and nutrition disorders		
Hypoglycaemia [*1]		

# participants affected / at risk	3/65 (4.62%)	6/26 (23.08%)
Musculoskeletal and connective tissue disorders		
Arthritis * 1		
# participants affected / at risk	0/65 (0.00%)	2/26 (7.69%)
Back Pain * 1		
# participants affected / at risk	1/65 (1.54%)	2/26 (7.69%)
Shoulder Pain * 1		
# participants affected / at risk	0/65 (0.00%)	2/26 (7.69%)
Nervous system disorders		
Dizziness * 1		
# participants affected / at risk	4/65 (6.15%)	1/26 (3.85%)
Respiratory, thoracic and mediastinal disorders		
Cough * 1		
# participants affected / at risk	4/65 (6.15%)	1/26 (3.85%)

* Events were collected by non-systematic assessment

1 Term from vocabulary, MedDRA (9.0)

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: Executive Vice President, Clinical and Quantitative Sciences
Organization: Merck Sharp & Dohme Corp
phone: 1-800-672-6372

Publications:

Chan JC, Scott R, Arjona Ferreira JC, Sheng D, Gonzalez E, Davies MJ, Stein PP, Kaufman KD, Amatruda JM, Williams-Herman D. Safety and efficacy of sitagliptin in patients with type 2 diabetes and chronic renal insufficiency. Diabetes Obes Metab. 2008 Jul;10(7):545-55. doi: 10.1111/j.1463-1326.2008.00914.x. Epub 2008 Jun 1.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00095056 History of Changes
Other Study ID Numbers:	0431-028 2004_054
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Last Updated:	March 12, 2015
Health Authority:	United States: Food and Drug Administration

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