ClinicalTrials.gov
A service of the U.S. National Institutes of Health

Example: "Heart attack" AND "Los Angeles"
Search for studies:
Search

Advanced Search | Help | Studies by Topic | Glossary

Find Studies | About Clinical Studies | Submit Studies | Resources | About This Site

Home > Find Studies > Search Results > Study Record Detail
Text Size

Trial record **1 of 1** for: NCT00509236
Previous Study | Return to List | Next Study

Sitagliptin Versus Glipizide in Participants With Type 2 Diabetes Mellitus and End-Stage Renal Disease (MK-0431-073 AM1)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

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

ClinicalTrials.gov Identifier:
NCT00509236

First received: July 27, 2007
Last updated: March 23, 2015
Last verified: March 2015
History of Changes

Full Text View | Tabular View | Study Results | Disclaimer | How to Read a Study Record

Purpose

The purpose of the study is to compare sitagliptin and glipizide in lowering blood sugar in participants with type-2 diabetes mellitus (T2DM) and end-stage renal disease on dialysis who do not have adequate glycemic control.

Condition	Intervention	Phase
Diabetes Mellitus, Type 2 End-Stage Kidney Disease	Drug: Sitagliptin Drug: Glipizide	Phase 3

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

Official Title: A Multicenter, Randomized Double-Blind Study to Evaluate the Efficacy and Safety of Sitagliptin Versus Glipizide in Participants With Type 2 Diabetes Mellitus and End-Stage Renal Disease Who Are on Dialysis and Who Have Inadequate Glycemic Control

Resource links provided by NLM:

MedlinePlus related topics: Diabetes Type 2 Kidney Diseases Kidney Failure

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 After Sitagliptin Treatment [Time Frame: Baseline / Week 54] [Designated as safety issue: No]

  Change from baseline in mean hemoglobin A1c after treatment with sitagliptin for 54 weeks. Hemoglobin A1c is the percent of hemoglobin that is glycated. Results for the glipizide arm are not reported in this table because the primary outcome measure is for the sitagliptin arm only.

- Number of Participants With Clinical Adverse Events [Time Frame: 54 Week Treatment Period + 28 days] [Designated as safety issue: Yes]

  Reported experiences assessed by investigators as adverse events, excluding data after initiation of glycemic rescue therapy.

Secondary Outcome Measures:

- Number of Participants With Symptomatic Hypoglycemic Adverse Events [Time Frame: 54 Week Treatment Period + 28 days] [Designated as safety issue: Yes]

  A symptomatic hypoglycemic adverse event is an episode with clinical symptoms attributed to hypoglycemia, without regard to fingerstick glucose level.

- Change From Baseline in Fasting Plasma Glucose (FPG) [Time Frame: Baseline / Week 54] [Designated as safety issue: No]

  Change from baseline in mean Fasting Plasma Glucose after treatment with sitagliptin versus glipizide for 54 weeks.

- Change From Baseline in Hemoglobin A1c for Sitagliptin Versus Glipizide Treatment [Time Frame: Baseline / Week 54] [Designated as safety issue: No]

  Change from baseline in least square means hemoglobin A1c after treatment with sitagliptin versus glipizide for 54 weeks. Hemoglobin A1c is the percent of hemoglobin that is glycated.

Enrollment:	129
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 25 mg	Drug: Sitagliptin 25 mg (one 25-mg tablet) once daily Other Name: MK-0431
Active Comparator: Glipizide 2.5 mg - 20 mg	Drug: Glipizide 2.5 mg (1/2 of a 5-mg tablet) once daily, up to 10 mg twice daily (four 5-mg tablets), for a maximum of 20 mg Other Name: Glucotrol

Eligibility

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

Criteria

Inclusion Criteria:

- Participant has T2DM.
- Participant is on dialysis on day of signing informed consent.
- Participant is unlikely to conceive or uses acceptable methods of birth control: hormonal contraceptive, intrauterine device (IUD), diaphragm with spermicide, contraceptive sponge, condom, or vasectomy.
- Participant has hemoglobin A1c ≥7% and ≤9% measured at or within 2 weeks prior to Visit 4/Week -2.
- Participant is ≥85% compliant with study medication during the single-blind placebo run-in (as determined by tablet/capsule count) and compliant with diet, exercise and other run-in treatments during the run-in period.

Exclusion Criteria:

- Participant has a history of type 1 diabetes mellitus or a history of ketoacidosis.
- Participant is losing weight in a weight loss program and is not in the maintenance phase (defined as <2 kg weight loss in 2 months), or intends to be involved in weight loss intervention outside that prescribed by the study.
- Participant has a clinically significant hematological disorder (e.g., aplastic anemia, myeloproliferative or myelodysplastic syndromes, thrombocytopenia).
- Participant has cirrhosis or active liver disease.
- Participant has been on dialysis for < 6 months.
- Participant has been diagnosed with a significant cardiovascular disorder and has new or worsening signs or symptoms of congestive heart failure within 3 months of signing informed consent.
- Participant has severe active peripheral vascular disease.
- Participant has a history of malignancy ≤ 5 years prior to signing informed consent, or > 5 years without documentation of remission/cure.
- Participant is under treatment for hyperthyroidism.
- Participant has a hypersensitivity or contraindication to glipizide.

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, Corry D, Mogensen CE, Sloan L, Xu L, Golm GT, Gonzalez EJ, Davies MJ, Kaufman KD, Goldstein BJ. Efficacy and safety of sitagliptin in patients with type 2 diabetes and ESRD receiving dialysis: a 54-week randomized trial. Am J Kidney Dis. 2013 Apr;61(4):579-87. doi: 10.1053/j.ajkd.2012.11.043. Epub 2013 Jan 24. Erratum in: Am J Kidney Dis. 2013 Oct;62(4):847.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00509236 History of Changes
Other Study ID Numbers:	0431-073 2007_550
Study First Received:	July 27, 2007
Results First Received:	February 13, 2012
Last Updated:	March 23, 2015
Health Authority:	United States: Food and Drug Administration

Additional relevant MeSH terms:

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

ClinicalTrials.gov processed this record on April 13, 2016

TO TOP

For Patients and Families | For Researchers | For Study Record Managers

HOME RSS FEEDS SITE MAP TERMS AND CONDITIONS DISCLAIMER CONTACT NLM HELP DESK

Copyright | Privacy | Accessibility | Viewers and Players | Freedom of Information Act | USA.gov
U.S. National Library of Medicine | U.S. National Institutes of Health | U.S. Department of Health and Human Services

ClinicalTrials.gov
A service of the U.S. National Institutes of Health

Example: "Heart attack" AND "Los Angeles"
Search for studies:
Search

Advanced Search | Help | Studies by Topic | Glossary

Find Studies | About Clinical Studies | Submit Studies | Resources | About This Site

Home > Find Studies > Search Results > Study Record Detail
Text Size

Trial record **1 of 1** for: NCT00509236
Previous Study | Return to List | Next Study

Sitagliptin Versus Glipizide in Participants With Type 2 Diabetes Mellitus and End-Stage Renal Disease (MK-0431-073 AM1)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

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

ClinicalTrials.gov Identifier:
NCT00509236

First received: July 27, 2007
Last updated: March 23, 2015
Last verified: March 2015
History of Changes

Full Text View | Tabular View | Study Results | Disclaimer | How to Read a Study Record

Results First Received: February 13, 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
Conditions:	Diabetes Mellitus, Type 2 End-Stage Kidney Disease
Interventions:	Drug: Sitagliptin Drug: 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
No text entered.

Reporting Groups

	Description
Sitagliptin 25 mg	One 25 mg tablet once daily for 54 weeks
Glipizide 2.5 mg - 20 mg	Between 2.5 mg - 20 mg daily for 54 weeks

Participant Flow: Overall Study

	Sitagliptin 25 mg	Glipizide 2.5 mg - 20 mg
STARTED	**64**	**65**
COMPLETED	**47**	**45**
NOT COMPLETED	**17**	**20**
Adverse Event	**7**	**9**
Withdrawal by Subject	**5**	**10**
Protocol Violation	**3**	**0**
Excluded Medication	**1**	**1**
Scheduled Kidney Transplant	**1**	**0**

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 25 mg	One 25 mg tablet once daily for 54 weeks
Glipizide 2.5 mg - 20 mg	Between 2.5 mg - 20 mg daily for 54 weeks
Total	Total of all reporting groups

Baseline Measures

	Sitagliptin 25 mg	Glipizide 2.5 mg - 20 mg	Total
Number of Participants [units: participants]	**64**	**65**	**129**
Age [units: years] Mean (Standard Deviation)	**60.5 (9.1)**	**58.5 (9.9)**	**59.5 (9.5)**
Gender [units: participants]			
Female	**24**	**28**	**52**

Male	**40**	**37**	**77**

Outcome Measures

Hide All Outcome Measures

1. Primary: Change From Baseline in Hemoglobin A1c After Sitagliptin Treatment [Time Frame: Baseline / Week 54]

Measure Type	Primary
Measure Title	Change From Baseline in Hemoglobin A1c After Sitagliptin Treatment
Measure Description	Change from baseline in mean hemoglobin A1c after treatment with sitagliptin for 54 weeks. Hemoglobin A1c is the percent of hemoglobin that is glycated. Results for the glipizide arm are not reported in this table because the primary outcome measure is for the sitagliptin arm only.
Time Frame	Baseline / 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.
Randomized participants. Numbers analyzed excluded participants with either no baseline or no post-baseline measurements. The last observation carried forward (LOCF) method was used to impute missing values.

Reporting Groups

	Description
Sitagliptin 25 mg	Participants received one 25 mg tablet once daily for 54 weeks

Measured Values

	Sitagliptin 25 mg
Number of Participants Analyzed [units: participants]	**62**
Change From Baseline in Hemoglobin A1c After Sitagliptin Treatment [units: Percent hemoglobin A1c] Mean (Standard Deviation)	
Baseline	**7.89 (0.74)**
Week 54	**7.15 (0.98)**
Change from Baseline at Week 54	**-0.74 (0.95)**

Statistical Analysis 1 for Change From Baseline in Hemoglobin A1c After Sitagliptin Treatment

Groups [1]	Sitagliptin 25 mg
Method [2]	ANCOVA
P Value [3]	<0.001

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	Model terms: treatment, prior diabetes pharmacotherapy (not on oral antihyperglycemic agent, or on oral antihyperglycemic agent), and a covariate for baseline A1c.
[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.

2. Primary: Number of Participants With Clinical Adverse Events [Time Frame: 54 Week Treatment Period + 28 days]

Measure Type	Primary
Measure Title	Number of Participants With Clinical Adverse Events
Measure Description	Reported experiences assessed by investigators as adverse events, excluding data after initiation of glycemic rescue therapy.
Time Frame	54 Week Treatment Period + 28 days
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 randomized participants.

Reporting Groups

	Description
Sitagliptin 25 mg	Participants received one 25 mg tablet once daily for 54 weeks
Glipizide 2.5 mg - 20 mg	Participants received between 2.5 mg - 20 mg daily for 54 weeks

Measured Values

	Sitagliptin 25 mg	Glipizide 2.5 mg - 20 mg
Number of Participants Analyzed [units: participants]	**64**	**65**
Number of Participants With Clinical Adverse Events [units: Participants]	**53**	**52**

Statistical Analysis 1 for Number of Participants With Clinical Adverse Events

Groups [1]	All groups
Difference in % Affected [2]	2.8
95% Confidence Interval	-10.9 to 16.5

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant estimation information:
	No text entered.

3. Secondary: Number of Participants With Symptomatic Hypoglycemic Adverse Events [Time Frame: 54 Week Treatment Period + 28 days]

Measure Type	Secondary
Measure Title	Number of Participants With Symptomatic Hypoglycemic Adverse Events
Measure Description	A symptomatic hypoglycemic adverse event is an episode with clinical symptoms attributed to hypoglycemia, without regard to fingerstick glucose level.
Time Frame	54 Week Treatment Period + 28 days
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 randomized participants.

Reporting Groups

	Description
Sitagliptin 25 mg	Participants received one 25 mg tablet once daily for 54 weeks
Glipizide 2.5 mg - 20 mg	Participants received between 2.5 mg - 20 mg daily for 54 weeks

Measured Values

	Sitagliptin 25 mg	Glipizide 2.5 mg - 20 mg
Number of Participants Analyzed [units: participants]	**64**	**65**
Number of Participants With Symptomatic Hypoglycemic Adverse Events [units: Participants]	**4**	**7**

Statistical Analysis 1 for Number of Participants With Symptomatic Hypoglycemic Adverse Events

Groups [1]	All groups
Method [2]	Miettinen & Nurminen
P Value [3]	0.336
Difference in % Affected [4]	-4.8
95% Confidence Interval	-15.7 to 5.6

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	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:
	Miettinen & Nurminen method stratified by prior diabetes pharmacotherapy (not on oral antihyperglycemic agent, or on oral antihyperglycemic agent).
[4]	Other relevant estimation information:
	No text entered.

4. Secondary: Change From Baseline in Fasting Plasma Glucose (FPG) [Time Frame: Baseline / Week 54]

Measure Type	Secondary
Measure Title	Change From Baseline in Fasting Plasma Glucose (FPG)
Measure Description	Change from baseline in mean Fasting Plasma Glucose after treatment with sitagliptin versus glipizide for 54 weeks.
Time Frame	Baseline / 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.
Randomized participants. Numbers analyzed excluded participants with no baseline or no post-baseline measurements. The last observation carried forward (LOCF) method was used to impute missing values.

Reporting Groups

	Description
Sitagliptin 25 mg	Participants received one 25 mg tablet once daily for 54 weeks
Glipizide 2.5 mg - 20 mg	Participants received between 2.5 mg - 20 mg daily for 54 weeks

Measured Values

	Sitagliptin 25 mg	Glipizide 2.5 mg - 20 mg
Number of Participants Analyzed [units: participants]	**60**	**59**
Change From Baseline in Fasting Plasma Glucose (FPG) [units: mg/dL] Mean (Standard Deviation)		
Baseline	**160.3 (48.5)**	**167.0 (56.2)**
Week 54	**135.8 (40.4)**	**134.0 (58.2)**

Change from Baseline to Week 54	**-24.5 (47.5)**	**-33.0 (55.9)**

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

Groups [1]	Sitagliptin 25 mg
Method [2]	ANCOVA
P Value [3]	<0.001
Change from Baseline in LS Mean [4]	-26.6
95% Confidence Interval	-38.0 to -15.3

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	Model terms: treatment, prior diabetes pharmacotherapy (not on oral antihyperglycemic agent, or on oral antihyperglycemic agent), and a covariate for baseline FPG.
[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:
	No text entered.

Statistical Analysis 2 for Change From Baseline in Fasting Plasma Glucose (FPG)

Groups [1]	Glipizide 2.5 mg - 20 mg
Method [2]	ANCOVA
P Value [3]	<0.001
Change from Baseline in LS Mean [4]	-31.2
95% Confidence Interval	-42.6 to -19.9

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	Model terms: treatment, prior diabetes pharmacotherapy (not on oral antihyperglycemic agent, or on oral antihyperglycemic agent), and a covariate for baseline FPG.
[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:
	No text entered.

Statistical Analysis 3 for Change From Baseline in Fasting Plasma Glucose (FPG)

Groups [1]	All groups

Difference in LS Means [2]	4.6
95% Confidence Interval	-11.5 to 20.7

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	Model terms: treatment, prior diabetes pharmacotherapy (not on oral antihyperglycemic agent, or on oral antihyperglycemic agent), and a covariate for baseline FPG.
[2]	Other relevant estimation information:
	No text entered.

5. Secondary: Change From Baseline in Hemoglobin A1c for Sitagliptin Versus Glipizide Treatment [Time Frame: Baseline / Week 54]

Measure Type	Secondary
Measure Title	Change From Baseline in Hemoglobin A1c for Sitagliptin Versus Glipizide Treatment
Measure Description	Change from baseline in least square means hemoglobin A1c after treatment with sitagliptin versus glipizide for 54 weeks. Hemoglobin A1c is the percent of hemoglobin that is glycated.
Time Frame	Baseline / 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.
Randomized participants. Numbers analyzed excluded participants with either no baseline or no post-baseline measurements. The last observation carried forward (LOCF) method was used to impute missing values.

Reporting Groups

	Description
Sitagliptin 25 mg	Participants received one 25 mg tablet once daily for 54 weeks
Glipizide 2.5 mg - 20 mg	Participants received between 2.5 mg - 20 mg daily for 54 weeks

Measured Values

	Sitagliptin 25 mg	**Glipizide 2.5 mg - 20 mg**
Number of Participants Analyzed [units: participants]	**62**	**59**
Change From Baseline in Hemoglobin A1c for Sitagliptin Versus Glipizide Treatment [units: Percent hemoglobin A1c] Least Squares Mean (95% Confidence Interval)	**-0.72 (-0.95 to -0.48)**	**-0.87 (-1.11 to -0.63)**

Statistical Analysis 1 for Change From Baseline in Hemoglobin A1c for Sitagliptin Versus Glipizide Treatment

Groups [1]	All groups
Method [2]	ANCOVA

Difference in LS Means [3]	0.15
95% Confidence Interval	-0.18 to 0.49

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	Model terms: treatment, prior diabetes pharmacotherapy (not on oral antihyperglycemic agent, or on oral antihyperglycemic agent), and a covariate for baseline A1c.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Other relevant estimation information:
	No text entered.

Serious Adverse Events

Hide Serious Adverse Events

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

Reporting Groups

	Description
Sitagliptin 25 mg	One 25 mg tablet once daily for 54 weeks
Glipizide 2.5 mg - 20 mg	Between 2.5 mg - 20 mg daily for 54 weeks

Serious Adverse Events

	Sitagliptin 25 mg	Glipizide 2.5 mg - 20 mg
Total, serious adverse events		
# participants affected / at risk	**23/64 (35.94%)**	**22/65 (33.85%)**
Blood and lymphatic system disorders		
Anaemia [1]		
# participants affected / at risk	**1/64 (1.56%)**	**0/65 (0.00%)**
# events	**1**	**0**
Cardiac disorders		
Acute myocardial infarction [1]		
# participants affected / at risk	**0/64 (0.00%)**	**1/65 (1.54%)**
# events	**0**	**1**
Angina pectoris [1]		
# participants affected / at risk	**0/64 (0.00%)**	**1/65 (1.54%)**
# events	**0**	**1**
1		

Bradycardia		
# participants affected / at risk	**1/64 (1.56%)**	**0/65 (0.00%)**
# events	**1**	**0**
Cardiac arrest [1]		
# participants affected / at risk	**0/64 (0.00%)**	**1/65 (1.54%)**
# events	**0**	**1**
Cardiac failure congestive [1]		
# participants affected / at risk	**1/64 (1.56%)**	**2/65 (3.08%)**
# events	**1**	**3**
Cardio-respiratory arrest [1]		
# participants affected / at risk	**0/64 (0.00%)**	**1/65 (1.54%)**
# events	**0**	**1**
Coronary artery stenosis [1]		
# participants affected / at risk	**0/64 (0.00%)**	**1/65 (1.54%)**
# events	**0**	**1**
Left ventricular dysfunstion [1]		
# participants affected / at risk	**1/64 (1.56%)**	**0/65 (0.00%)**
# events	**1**	**0**
Myocardial infarction [1]		
# participants affected / at risk	**1/64 (1.56%)**	**1/65 (1.54%)**
# events	**1**	**1**
Ventricular fibrillation [1]		
# participants affected / at risk	**1/64 (1.56%)**	**0/65 (0.00%)**
# events	**1**	**0**
Gastrointestinal disorders		
Abdominal adhesions [1]		
# participants affected / at risk	**1/64 (1.56%)**	**0/65 (0.00%)**
# events	**1**	**0**
Duodenal ulcer [1]		
# participants affected / at risk	**1/64 (1.56%)**	**0/65 (0.00%)**
# events	**1**	**0**
Enteritis [1]		
# participants affected / at risk	**1/64 (1.56%)**	**0/65 (0.00%)**
# events	**1**	**0**
Gastritis [1]		
# participants affected / at risk	**1/64 (1.56%)**	**1/65 (1.54%)**
# events	**1**	**1**
Intestinal perforation [1]		
# participants affected / at risk	**0/64 (0.00%)**	**1/65 (1.54%)**
# events	**0**	**1**
Peritonitis [1]		
# participants affected / at risk	**0/64 (0.00%)**	**2/65 (3.08%)**
# events	**0**	**2**
Upper gastrointestinal haemorrhage [1]		
# participants affected / at risk	**0/64 (0.00%)**	**1/65 (1.54%)**

# events	0	1
General disorders		
Device malfunction [1]		
# participants affected / at risk	2/64 (3.13%)	0/65 (0.00%)
# events	2	0
Device occlusion [1]		
# participants affected / at risk	1/64 (1.56%)	1/65 (1.54%)
# events	1	1
Medical device complication [1]		
# participants affected / at risk	1/64 (1.56%)	0/65 (0.00%)
# events	2	0
Pyrexia [1]		
# participants affected / at risk	1/64 (1.56%)	0/65 (0.00%)
# events	1	0
Infections and infestations		
Abdominal sepsis [1]		
# participants affected / at risk	0/64 (0.00%)	1/65 (1.54%)
# events	0	1
Arteriovenous fistula site infection [1]		
# participants affected / at risk	0/64 (0.00%)	1/65 (1.54%)
# events	0	1
Bronchopneumonia [1]		
# participants affected / at risk	0/64 (0.00%)	1/65 (1.54%)
# events	0	1
Catheter site infection [1]		
# participants affected / at risk	0/64 (0.00%)	4/65 (6.15%)
# events	0	4
Cellulitis [1]		
# participants affected / at risk	1/64 (1.56%)	0/65 (0.00%)
# events	1	0
Clostridium difficile colitis [1]		
# participants affected / at risk	0/64 (0.00%)	1/65 (1.54%)
# events	0	1
Device related infection [1]		
# participants affected / at risk	1/64 (1.56%)	2/65 (3.08%)
# events	1	2
Device related sepsis [1]		
# participants affected / at risk	0/64 (0.00%)	1/65 (1.54%)
# events	0	3
Diabetic foot infection [1]		
# participants affected / at risk	0/64 (0.00%)	1/65 (1.54%)
# events	0	1
Gastroenteritis [1]		
# participants affected / at risk	2/64 (3.13%)	1/65 (1.54%)
# events	3	1

Necrotising fasciitis [1]		
# participants affected / at risk	**1/64 (1.56%)**	**0/65 (0.00%)**
# events	**1**	**0**
Pneumonia [1]		
# participants affected / at risk	**0/64 (0.00%)**	**1/65 (1.54%)**
# events	**0**	**1**
Pulmonary tuberculosis [1]		
# participants affected / at risk	**1/64 (1.56%)**	**0/65 (0.00%)**
# events	**1**	**0**
Septic shock [1]		
# participants affected / at risk	**2/64 (3.13%)**	**0/65 (0.00%)**
# events	**2**	**0**
Streptococcal bacteraemia [1]		
# participants affected / at risk	**0/64 (0.00%)**	**2/65 (3.08%)**
# events	**0**	**2**
Tonsillitis [1]		
# participants affected / at risk	**1/64 (1.56%)**	**0/65 (0.00%)**
# events	**1**	**0**
Urinary tract infection [1]		
# participants affected / at risk	**2/64 (3.13%)**	**1/65 (1.54%)**
# events	**2**	**1**
Injury, poisoning and procedural complications		
Arteriovenous fistula thrombosis [1]		
# participants affected / at risk	**1/64 (1.56%)**	**1/65 (1.54%)**
# events	**1**	**1**
Arteriovenous graft site haemorrhage [1]		
# participants affected / at risk	**0/64 (0.00%)**	**1/65 (1.54%)**
# events	**0**	**1**
Hip fracture [1]		
# participants affected / at risk	**1/64 (1.56%)**	**0/65 (0.00%)**
# events	**1**	**0**
Joint injury [1]		
# participants affected / at risk	**0/64 (0.00%)**	**1/65 (1.54%)**
# events	**0**	**1**
Pelvic fracture [1]		
# participants affected / at risk	**1/64 (1.56%)**	**0/65 (0.00%)**
# events	**1**	**0**
Subdural haematoma [1]		
# participants affected / at risk	**2/64 (3.13%)**	**0/65 (0.00%)**
# events	**2**	**0**
Vascular graft thrombosis [1]		
# participants affected / at risk	**1/64 (1.56%)**	**0/65 (0.00%)**
# events	**1**	**0**
Investigations		
Liver function test abnormal [1]		

# participants affected / at risk	0/64 (0.00%)	1/65 (1.54%)
# events	0	1
Metabolism and nutrition disorders		
Diabetic foot [1]		
# participants affected / at risk	1/64 (1.56%)	0/65 (0.00%)
# events	1	0
Fluid overload [1]		
# participants affected / at risk	1/64 (1.56%)	2/65 (3.08%)
# events	2	4
Hypercalcaemia [1]		
# participants affected / at risk	0/64 (0.00%)	1/65 (1.54%)
# events	0	1
Hyponatraemia [1]		
# participants affected / at risk	1/64 (1.56%)	0/65 (0.00%)
# events	1	0
Musculoskeletal and connective tissue disorders		
Back pain [1]		
# participants affected / at risk	0/64 (0.00%)	1/65 (1.54%)
# events	0	1
Costochondritis [1]		
# participants affected / at risk	0/64 (0.00%)	1/65 (1.54%)
# events	0	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Prostate cancer [1]		
# participants affected / at risk	1/64 (1.56%)	0/65 (0.00%)
# events	1	0
Respiratory, thoracic and mediastinal disorders		
Acute pulmonary oedema [1]		
# participants affected / at risk	2/64 (3.13%)	0/65 (0.00%)
# events	2	0
Haemothorax [1]		
# participants affected / at risk	1/64 (1.56%)	0/65 (0.00%)
# events	1	0
Pleural effusion [1]		
# participants affected / at risk	0/64 (0.00%)	1/65 (1.54%)
# events	0	1
Pleuritic pain [1]		
# participants affected / at risk	1/64 (1.56%)	0/65 (0.00%)
# events	1	0
Skin and subcutaneous tissue disorders		
Decubitus ulcer [1]		
# participants affected / at risk	0/64 (0.00%)	1/65 (1.54%)
# events	0	1
Vascular disorders		

Aortic dissection [1]		
# participants affected / at risk	**1/64 (1.56%)**	**0/65 (0.00%)**
# events	**1**	**0**
Hypotension [1]		
# participants affected / at risk	**1/64 (1.56%)**	**1/65 (1.54%)**
# events	**2**	**2**
Peripheral vascular disorder [1]		
# participants affected / at risk	**0/64 (0.00%)**	**1/65 (1.54%)**
# events	**0**	**1**

1 Term from vocabulary, MedDRA (13.1)

Other Adverse Events

Hide Other Adverse Events

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

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Sitagliptin 25 mg	One 25 mg tablet once daily for 54 weeks
Glipizide 2.5 mg - 20 mg	Between 2.5 mg - 20 mg daily for 54 weeks

Other Adverse Events

	Sitagliptin 25 mg	**Glipizide 2.5 mg - 20 mg**
Total, other (not including serious) adverse events		
# participants affected / at risk	**33/64 (51.56%)**	**37/65 (56.92%)**
Gastrointestinal disorders		
Diarrhoea [1]		
# participants affected / at risk	**2/64 (3.13%)**	**5/65 (7.69%)**
# events	**2**	**6**
Vomiting [1]		
# participants affected / at risk	**4/64 (6.25%)**	**2/65 (3.08%)**
# events	**6**	**2**
General disorders		
Oedema peripheral [1]		

# participants affected / at risk	1/64 (1.56%)	5/65 (7.69%)
# events	1	5
Infections and infestations		
Upper respiratory tract infection [1]		
# participants affected / at risk	3/64 (4.69%)	7/65 (10.77%)
# events	3	8
Urinary tract infection [1]		
# participants affected / at risk	5/64 (7.81%)	1/65 (1.54%)
# events	6	1
Investigations		
Blood glucose decreased [1]		
# participants affected / at risk	11/64 (17.19%)	18/65 (27.69%)
# events	37	94
Blood glucose increased [1]		
# participants affected / at risk	4/64 (6.25%)	5/65 (7.69%)
# events	11	13
Metabolism and nutrition disorders		
Hypoglycaemia [1]		
# participants affected / at risk	4/64 (6.25%)	7/65 (10.77%)
# events	7	16
Nervous system disorders		
Headache [1]		
# participants affected / at risk	4/64 (6.25%)	0/65 (0.00%)
# events	4	0
Respiratory, thoracic and mediastinal disorders		
Cough [1]		
# participants affected / at risk	7/64 (10.94%)	6/65 (9.23%)
# events	7	7
Vascular disorders		
Hypertension [1]		
# participants affected / at risk	5/64 (7.81%)	6/65 (9.23%)
# events	7	6
Hypotension [1]		
# participants affected / at risk	4/64 (6.25%)	1/65 (1.54%)
# events	7	1

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:** Subsequent to the multicenter publication, or 24 months after completion of the study, whichever comes first, an investigator and/or colleagues may publish the results for their study site independently. 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, Corry D, Mogensen CE, Sloan L, Xu L, Golm GT, Gonzalez EJ, Davies MJ, Kaufman KD, Goldstein BJ. Efficacy and safety of sitagliptin in patients with type 2 diabetes and ESRD receiving dialysis: a 54-week randomized trial. Am J Kidney Dis. 2013 Apr;61(4):579-87. doi: 10.1053/j.ajkd.2012.11.043. Epub 2013 Jan 24. Erratum in: Am J Kidney Dis. 2013 Oct;62(4):847.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00509236 History of Changes
Other Study ID Numbers:	0431-073 2007_550 (Other Identifier: Merck Study Number)
Study First Received:	July 27, 2007
Results First Received:	February 13, 2012
Last Updated:	March 23, 2015
Health Authority:	United States: Food and Drug Administration

TO TOP

For Patients and Families | For Researchers | For Study Record Managers

HOME RSS FEEDS SITE MAP TERMS AND CONDITIONS DISCLAIMER CONTACT NLM HELP DESK

Copyright | Privacy | Accessibility | Viewers and Players | Freedom of Information Act | USA.gov
U.S. National Library of Medicine | U.S. National Institutes of Health | U.S. Department of Health and Human Services