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: NCT00094770
Previous Study | Return to List | Next Study

An Investigational Drug Study in Patients With Type 2 Diabetes Mellitus (0431-024)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

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

ClinicalTrials.gov Identifier:
NCT00094770

First received: October 22, 2004
Last updated: April 27, 2015
Last verified: April 2015
History of Changes

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

Purpose

The purpose of this investigational study is to determine the safety and effectiveness of an investigational drug in patients with type 2 diabetes mellitus (a specific type of diabetes).

Condition	Intervention	Phase
Diabetes Mellitus, Type 2	Drug: sitagliptin (MK0431) Drug: Comparator: 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, Double-Blind, Randomized Study to Evaluate the Safety and Efficacy of the Addition of MK0431 Compared With Sulfonylurea Therapy in Patients With Type 2 Diabetes With Inadequate Glycemic Control on Metformin Monotherapy

Resource links provided by NLM:

MedlinePlus related topics: 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 HbA1c at Week 52 [Time Frame: Baseline and Week 52] [Designated as safety issue: No]

HbA1c is measured as percent. Thus, this change from baseline reflects the Week 52 HbA1c percent minus the Week 0 HbA1c percent.

Secondary Outcome Measures:

- Change From Baseline in HbA1c at Week 104 [Time Frame: Baseline and Week 104] [Designated as safety issue: No]
  HbA1c is measured as percent. Thus, this change from baseline reflects the Week 104 HbA1c percent minus the Week 0 HbA1c percent.
- Change From Baseline in Body Weight at Week 52 [Time Frame: Baseline and Week 52] [Designated as safety issue: Yes]
  Change from baseline at Week 52 is defined as Week 52 minus Week 0.
- Change From Baseline in Body Weight at Week 104 [Time Frame: Baseline and Week 104] [Designated as safety issue: Yes]
  Change from baseline at Week 104 is defined as Week 104 minus Week 0.
- Hypoglycemic Events at Week 52 [Time Frame: Baseline to Week 52] [Designated as safety issue: Yes]
  Number of participants who reported 1 or more episodes of the adverse experience (AEs) of hypoglycemia.
- Hypoglycemic Events at Week 104 [Time Frame: Baseline to Week 104] [Designated as safety issue: Yes]
  Number of participants who reported 1 or more episodes of the adverse experience of hypoglycemia.
- Number of Participants With Clinical Adverse Experiences (CAEs) at Week 104 [Time Frame: Baseline to Week 104] [Designated as safety issue: Yes]
  An adverse experience (AE) is defined as any unfavorable and unintended change in the structure, function, or chemistry of the body temporally associated with the use of the SPONSOR'S product, whether or not considered related to the use of the product.
- Number of Participants With Serious CAEs at Week 104 [Time Frame: Baseline to Week 104] [Designated as safety issue: Yes]
  Serious CAEs are any AEs occurring at any dose that; Results in death; or Is life threatening; or Results in a persistent or significant disability/incapacity; or Results in or prolongs an existing inpatient hospitalization; or Is a congenital anomaly/birth defect; or Is a cancer; or Is an overdose.
- Number of Participants With Drug-related CAEs at Week 104 [Time Frame: Baseline to Week 104] [Designated as safety issue: Yes]
  Participants with drug-related (as assessed by an investigator who is a qualified physician according to his/her best clinical judgment) CAEs.
- Number of Participants With Laboratory Adverse Experiences (LAEs) at Week 104 [Time Frame: Baseline to Week 104] [Designated as safety issue: Yes]
  A laboratory adverse experience (LAE) is defined as any unfavorable and unintended change in the chemistry of the body temporally associated with the use of the SPONSOR'S product, whether or not considered related to the use of the product.
- Number of Participants With Serious LAEs at Week 104 [Time Frame: Baseline to Week 104] [Designated as safety issue: Yes]
  Serious LAEs are any LAEs occurring at any dose that: results in death; or is life threatening; or results in a persistent or significant disability/incapacity; or results in or prolongs an existing inpatient hospitalization; or is a congenital anomaly/birth defect; or is a cancer; or is an overdose.
- Number of Participants With Drug-related LAEs at Week 104 [Time Frame: Baseline to Week 104] [Designated as safety issue: Yes]
  Participants with drug-related (as assessed by an investigator who is a qualified physician according to his/her best clinical judgment) LAEs.

Enrollment:	1172
Study Start Date:	September 2004
Study Completion Date:	May 2007
Primary Completion Date:	May 2006 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: Sitagliptin 100 mg Sitagliptin 100 mg oral tablets of sitagliptin once daily.	Drug: sitagliptin (MK0431) Sitagliptin 100 mg oral tablets of sitagliptin once daily.

	Other Name: MK0431
Active Comparator: Glipizide Glipizide 1 tablet (5 mg) per day. Patients could then up-titrated to a total daily dose of 4 tablets twice daily (20mg/day) based on their glycemic control.	Drug: Comparator: glipizide Glipizide 1 tablet (5 mg) per day. Patients could then up-titrated to a total daily dose of 4 tablets twice daily (20mg/day) based on their glycemic control. Other Name: Glipizide

Detailed Description:

The duration of treatment is 104 weeks.

Eligibility

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

Criteria

Inclusion Criteria:

- Patients who are at least 18 years of age and not older than 78 with type 2 diabetes mellitus

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: NCT00094770

Sponsors and Collaborators

Merck Sharp & Dohme Corp.

Investigators

Study Director: Medical Monitor Merck Sharp & Dohme Corp.

More Information

Publications:

Nauck MA, Meininger G, Sheng D, Terranella L, Stein PP; Sitagliptin Study 024 Group. Efficacy and safety of the dipeptidyl peptidase-4 inhibitor, sitagliptin, compared with the sulfonylurea, glipizide, in patients with type 2 diabetes inadequately controlled on metformin alone: a randomized, double-blind, non-inferiority trial. Diabetes Obes Metab. 2007 Mar;9(2):194-205.

Publications automatically indexed to this study by ClinicalTrials.gov Identifier (NCT Number):

Seck TL, Engel SS, Williams-Herman DE, Sisk CM, Golm GT, Wang H, Kaufman KD, Goldstein BJ. Sitagliptin more effectively achieves a composite endpoint for A1C reduction, lack of hypoglycemia and no body weight gain compared with glipizide. Diabetes Res Clin Pract. 2011 Jul;93(1):e15-7. doi: 10.1016/j.diabres.2011.03.006. Epub 2011 Apr 8.

Seck T, Nauck M, Sheng D, Sunga S, Davies MJ, Stein PP, Kaufman KD, Amatruda JM; Sitagliptin Study 024 Group. Safety and efficacy of treatment with sitagliptin or glipizide in patients with type 2 diabetes inadequately controlled on metformin: a 2-year study. Int J Clin Pract. 2010 Apr;64(5):562-76. doi: 10.1111/j.1742-1241.2010.02353.x.

Responsible Party: Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier: NCT00094770 History of Changes
Other Study ID Numbers: 0431-024 MK0431-024 2004_049
Study First Received: October 22, 2004
Results First Received: September 24, 2009
Last Updated: April 27, 2015

Health Authority: United States: Food and Drug Administration

Additional relevant MeSH terms:

Diabetes Mellitus
Diabetes Mellitus, Type 2
Endocrine System Diseases
Glucose Metabolism Disorders
Metabolic Diseases
Glipizide
Sitagliptin
Dipeptidyl-Peptidase IV Inhibitors
Enzyme Inhibitors
Hormones
Hormones, Hormone Substitutes, and Hormone Antagonists
Hypoglycemic Agents
Incretins
Molecular Mechanisms of Pharmacological Action
Pharmacologic Actions
Physiological Effects of Drugs
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: NCT00094770
Previous Study | Return to List | Next Study

An Investigational Drug Study in Patients With Type 2 Diabetes Mellitus (0431-024)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

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

ClinicalTrials.gov Identifier:
NCT00094770

First received: October 22, 2004
Last updated: April 27, 2015
Last verified: April 2015
History of Changes

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

Results First Received: September 24, 2009

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Investigator); Primary Purpose: Treatment
Condition:	Diabetes Mellitus, Type 2
Interventions:	Drug: sitagliptin (MK0431) Drug: Comparator: 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

Phase III

First Patient In: 26-Oct-2004; Last Patient Last Visit: 17-May-2007; 173 medical clinics worldwide.

Pre-Assignment Details

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

Participants 18-78 years of age with type 2 diabetes mellitus (T2DM) and inadequate glycemic control (Hemoglobin A1c >6.5% and < 10%) on metformin at a dose of >1500mg/day.

Reporting Groups

	Description
Sitagliptin 100 mg	The Sitagliptin 100 mg group includes data from patients randomized to receive treatment with 100 mg oral tablets of sitagliptin once daily.
Glipizide	The Glipizide group includes data from patients randomized to receive treatment with glipizide initiated at a dose of 1 tablet (5 mg) per day. Patients could then up-titrated to a total daily dose of 4 tablets twice daily (20mg/day) based on their glycemic control.

Participant Flow for 2 periods

Period 1: Year 1 (Week 0 to Week 52)

	Sitagliptin 100 mg	Glipizide
STARTED	588	584
COMPLETED	386 [1]	412 [2]
NOT COMPLETED	202	172
Adverse Event	25	26
Lack of Efficacy	86	58
Lost to Follow-up	19	10
Protocol Violation	10	10
Protocol Specified Discontinuation	19	25
Patient Moved	6	2
Withdrawal by Subject	25	28
Site Terminated	2	2
Unspecified	10	11

[1] 4 Participants who Completed Week 52, Did NOT Enter second year
[2] 11 Participants who Completed Week 52, Did NOT Enter second year

Period 2: Year 2 (Week 0 to Week 104)

	Sitagliptin 100 mg	Glipizide
STARTED	588	584
COMPLETED	255	264
NOT COMPLETED	333	320
Adverse Event	35	36
Lack of Efficacy	180	162
Lost to Follow-up	25	15
Protocol Violation	13	12

Protocol Specified Discontinuation	**29**	**30**
Patient Moved	**6**	**2**
Withdrawal by Subject	**28**	**38**
Site Terminated	**2**	**2**
Unspecified	**15**	**23**

Baseline Characteristics

Hide Baseline Characteristics

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
No text entered.

Reporting Groups

	Description
Sitagliptin 100 mg	The Sitagliptin 100 mg group includes data from patients randomized to receive treatment with 100 mg oral tablets of sitagliptin once daily.
Glipizide	The Glipizide group includes data from patients randomized to receive treatment with glipizide initiated at a dose of 1 tablet (5 mg) per day. Patients could then up-titrated to a total daily dose of 4 tablets twice daily (20mg/day) based on their glycemic control.
Total	Total of all reporting groups

Baseline Measures

	Sitagliptin 100 mg	**Glipizide**	**Total**
Number of Participants [units: participants]	**588**	**584**	**1172**
Age [units: years] Mean (Standard Deviation)	**56.8 (9.3)**	**56.6 (9.8)**	**56.7 (9.55)**
Gender [units: participants]			
Female	**252**	**226**	**478**
Male	**336**	**358**	**694**
Race/Ethnicity, Customized [units: participants]			
Asian	**50**	**49**	**99**
Black	**41**	**35**	**76**
Hispanic	**43**	**46**	**89**
White	**432**	**434**	**866**
Other	**22**	**20**	**42**

Hemoglobin A1c (HbA1c) [units: Percent] Mean (Standard Deviation)	**7.7 (0.9)**	**7.6 (0.9)**	**7.7 (0.9)**

Outcome Measures

Hide All Outcome Measures

1. Primary: Change From Baseline in HbA1c at Week 52 [Time Frame: Baseline and Week 52]

Measure Type	Primary
Measure Title	Change From Baseline in HbA1c at Week 52
Measure Description	HbA1c is measured as percent. Thus, this change from baseline reflects the Week 52 HbA1c percent minus the Week 0 HbA1c percent.
Time Frame	Baseline and Week 52
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 52, and did not have any major protocol violations (e.g. drug compliance < 75%, addition of prohibited antihyperglycemic agent, incorrect double-blind study medication). No missing data were imputed.

Reporting Groups

	Description
Sitagliptin 100 mg	The Sitagliptin 100 mg group includes data from patients randomized to receive treatment with 100 mg oral tablets of sitagliptin once daily.
Glipizide	The Glipizide group includes data from patients randomized to receive treatment with glipizide initiated at a dose of 1 tablet (5 mg) per day. Patients could then up-titrated to a total daily dose of 4 tablets twice daily (20mg/day) based on their glycemic control.

Measured Values

	Sitagliptin 100 mg	**Glipizide**
Number of Participants Analyzed [units: participants]	**382**	**411**
Change From Baseline in HbA1c at Week 52 [units: Percent] Least Squares Mean (95% Confidence Interval)	**-0.67 (-0.75 to -0.59)**	**-0.67 (-0.75 to -0.59)**

No statistical analysis provided for Change From Baseline in HbA1c at Week 52

2. Secondary: Change From Baseline in HbA1c at Week 104 [Time Frame: Baseline and Week 104]

Measure Type	Secondary
Measure Title	Change From Baseline in HbA1c at Week 104

Measure Description	HbA1c is measured as percent. Thus, this change from baseline reflects the Week 104 HbA1c percent minus the Week 0 HbA1c percent.
Time Frame	Baseline and Week 104
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 104, and did not have any major protocol violations (e.g. drug compliance < 75%, addition of prohibited antihyperglycemic agent, incorrect double-blind study medication). No missing data were imputed.

Reporting Groups

	Description
Sitagliptin 100 mg	The Sitagliptin 100 mg group includes data from patients randomized to receive treatment with 100 mg oral tablets of sitagliptin once daily.
Glipizide	The Glipizide group includes data from patients randomized to receive treatment with glipizide initiated at a dose of 1 tablet (5 mg) per day. Patients could then up-titrated to a total daily dose of 4 tablets twice daily (20mg/day) based on their glycemic control.

Measured Values

	Sitagliptin 100 mg	**Glipizide**
Number of Participants Analyzed [units: participants]	**248**	**256**
Change From Baseline in HbA1c at Week 104 [units: Percent] Least Squares Mean (95% Confidence Interval)	**-0.54 (-0.64 to -0.45)**	**-0.51 (-0.60 to -0.42)**

No statistical analysis provided for Change From Baseline in HbA1c at Week 104

3. Secondary: Change From Baseline in Body Weight at Week 52 [Time Frame: Baseline and Week 52]

Measure Type	Secondary
Measure Title	Change From Baseline in Body Weight at Week 52
Measure Description	Change from baseline at Week 52 is defined as Week 52 minus Week 0.
Time Frame	Baseline and Week 52
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The All-Patient-as-Treated (APaT) population required that a participant received at least 1 dose of double-blind study therapy. No missing data were imputed.

Reporting Groups

	Description
Sitagliptin 100 mg	The Sitagliptin 100 mg group includes data from patients randomized to receive treatment with 100 mg oral tablets of sitagliptin once daily.
Glipizide	The Glipizide group includes data from patients randomized to receive treatment with glipizide initiated at a dose of 1 tablet (5 mg) per day. Patients could then up-titrated to a total daily dose of 4 tablets twice daily (20mg/day) based on their glycemic control.

Measured Values

	Sitagliptin 100 mg	Glipizide
Number of Participants Analyzed [units: participants]	**389**	**416**
Change From Baseline in Body Weight at Week 52 [units: Kilograms] Least Squares Mean (95% Confidence Interval)	**-1.5 (-2.0 to -0.9)**	**1.1 (0.5 to 1.6)**

No statistical analysis provided for Change From Baseline in Body Weight at Week 52

4. Secondary: Change From Baseline in Body Weight at Week 104 [Time Frame: Baseline and Week 104]

Measure Type	Secondary
Measure Title	Change From Baseline in Body Weight at Week 104
Measure Description	Change from baseline at Week 104 is defined as Week 104 minus Week 0.
Time Frame	Baseline and Week 104
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The All-Patient-as-Treated (APaT) population required that a participant received at least 1 dose of double-blind study therapy. No missing data were imputed.

Reporting Groups

	Description
Sitagliptin 100 mg	The Sitagliptin 100 mg group includes data from patients randomized to receive treatment with 100 mg oral tablets of sitagliptin once daily.
Glipizide	The Glipizide group includes data from patients randomized to receive treatment with glipizide initiated at a dose of 1 tablet (5 mg) per day. Patients could then up-titrated to a total daily dose of 4 tablets twice daily (20mg/day) based on their glycemic control.

Measured Values

	Sitagliptin 100 mg	Glipizide
Number of Participants Analyzed	**253**	**261**

[units: participants]		
Change From Baseline in Body Weight at Week 104 [units: Kilograms] Least Squares Mean (95% Confidence Interval)	**-1.6 (-2.3 to -1.0)**	**0.7 (0.0 to 1.3)**

No statistical analysis provided for Change From Baseline in Body Weight at Week 104

5. Secondary: Hypoglycemic Events at Week 52 [Time Frame: Baseline to Week 52]

Measure Type	Secondary
Measure Title	Hypoglycemic Events at Week 52
Measure Description	Number of participants who reported 1 or more episodes of the adverse experience (AEs) of hypoglycemia.
Time Frame	Baseline to Week 52
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 who received at least 1 dose of the double-blind study therapy.

Reporting Groups

	Description
Sitagliptin 100 mg	The Sitagliptin 100 mg group includes data from patients randomized to receive treatment with 100 mg oral tablets of sitagliptin once daily.
Glipizide	The Glipizide group includes data from patients randomized to receive treatment with glipizide initiated at a dose of 1 tablet (5 mg) per day. Patients could then up-titrated to a total daily dose of 4 tablets twice daily (20mg/day) based on their glycemic control.

Measured Values

	Sitagliptin 100 mg	**Glipizide**
Number of Participants Analyzed [units: participants]	**588**	**584**
Hypoglycemic Events at Week 52 [units: Participants]		
Participants with one or more Hypoglycemic AEs	**29**	**187**
Total number of Hypoglycemic episodes	**50**	**657**
Participants with no Hypoglycemic AEs	**559**	**397**

No statistical analysis provided for Hypoglycemic Events at Week 52

6. Secondary: Hypoglycemic Events at Week 104 [Time Frame: Baseline to Week 104]

Measure Type	Secondary
Measure Title	Hypoglycemic Events at Week 104
Measure Description	Number of participants who reported 1 or more episodes of the adverse experience of hypoglycemia.
Time Frame	Baseline to Week 104
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 who received at least 1 dose of the double-blind study therapy.

Reporting Groups

	Description
Sitagliptin 100 mg	The Sitagliptin 100 mg group includes data from patients randomized to receive treatment with 100 mg oral tablets of sitagliptin once daily.
Glipizide	The Glipizide group includes data from patients randomized to receive treatment with glipizide initiated at a dose of 1 tablet (5 mg) per day. Patients could then up-titrated to a total daily dose of 4 tablets twice daily (20mg/day) based on their glycemic control.

Measured Values

	Sitagliptin 100 mg	**Glipizide**
Number of Participants Analyzed [units: participants]	**588**	**584**
Hypoglycemic Events at Week 104 [units: Participants]		
Participants with one or more Hypoglycemic AEs	**31**	**199**
Total number of Hypoglycemic episodes	**57**	**805**
Participants with no Hypoglycemic AEs	**557**	**385**

No statistical analysis provided for Hypoglycemic Events at Week 104

7. Secondary: Number of Participants With Clinical Adverse Experiences (CAEs) at Week 104 [Time Frame: Baseline to Week 104]

Measure Type	Secondary
Measure Title	Number of Participants With Clinical Adverse Experiences (CAEs) at Week 104
Measure Description	An adverse experience (AE) is defined as any unfavorable and unintended change in the structure, function, or chemistry of the body temporally associated with the use of the SPONSOR'S product, whether or not considered related to the use of the product.
Time Frame	Baseline to Week 104
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 who received at least 1 dose of the double-blind study therapy.

Reporting Groups

	Description
Sitagliptin 100 mg	The Sitagliptin 100 mg group includes data from patients randomized to receive treatment with 100 mg oral tablets of sitagliptin once daily.
Glipizide	The Glipizide group includes data from patients randomized to receive treatment with glipizide initiated at a dose of 1 tablet (5 mg) per day. Patients could then up-titrated to a total daily dose of 4 tablets twice daily (20mg/day) based on their glycemic control.

Measured Values

	Sitagliptin 100 mg	**Glipizide**
Number of Participants Analyzed [units: participants]	**588**	**584**
Number of Participants With Clinical Adverse Experiences (CAEs) at Week 104 [units: Participants]		
With CAES	**452**	**480**
Without CAES	**136**	**104**

No statistical analysis provided for Number of Participants With Clinical Adverse Experiences (CAEs) at Week 104

8. Secondary: Number of Participants With Serious CAEs at Week 104 [Time Frame: Baseline to Week 104]

Measure Type	Secondary
Measure Title	Number of Participants With Serious CAEs at Week 104
Measure Description	Serious CAEs are any AEs occurring at any dose that; Results in death; or Is life threatening; or Results in a persistent or significant disability/incapacity; or Results in or prolongs an existing inpatient hospitalization; or Is a congenital anomaly/birth defect; or Is a cancer; or Is an overdose.
Time Frame	Baseline to Week 104
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 who received at least 1 dose of the double-blind study therapy.

Reporting Groups

	Description
Sitagliptin 100 mg	The Sitagliptin 100 mg group includes data from patients randomized to receive treatment with 100 mg oral tablets of sitagliptin once daily.

Glipizide	The Glipizide group includes data from patients randomized to receive treatment with glipizide initiated at a dose of 1 tablet (5 mg) per day. Patients could then up-titrated to a total daily dose of 4 tablets twice daily (20mg/day) based on their glycemic control.

Measured Values

	Sitagliptin 100 mg	Glipizide
Number of Participants Analyzed [units: participants]	**588**	**584**
Number of Participants With Serious CAEs at Week 104 [units: Participants]		
With serious CAEs	**64**	**73**
Without serious CAEs	**524**	**511**

No statistical analysis provided for Number of Participants With Serious CAEs at Week 104

9. Secondary: Number of Participants With Drug-related CAEs at Week 104 [Time Frame: Baseline to Week 104]

Measure Type	Secondary
Measure Title	Number of Participants With Drug-related CAEs at Week 104
Measure Description	Participants with drug-related (as assessed by an investigator who is a qualified physician according to his/her best clinical judgment) CAEs.
Time Frame	Baseline to Week 104
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 who received at least 1 dose of the double-blind study therapy.

Reporting Groups

	Description
Sitagliptin 100 mg	The Sitagliptin 100 mg group includes data from patients randomized to receive treatment with 100 mg oral tablets of sitagliptin once daily.
Glipizide	The Glipizide group includes data from patients randomized to receive treatment with glipizide initiated at a dose of 1 tablet (5 mg) per day. Patients could then up-titrated to a total daily dose of 4 tablets twice daily (20mg/day) based on their glycemic control.

Measured Values

	Sitagliptin 100 mg	Glipizide
Number of Participants Analyzed [units: participants]	**588**	**584**
Number of Participants With Drug-related CAEs at Week 104		

[units: Participants]		
With drug related CAEs	97	193
Without drug related CAEs	491	391

No statistical analysis provided for Number of Participants With Drug-related CAEs at Week 104

10. Secondary: Number of Participants With Laboratory Adverse Experiences (LAEs) at Week 104 [Time Frame: Baseline to Week 104]

Measure Type	Secondary
Measure Title	Number of Participants With Laboratory Adverse Experiences (LAEs) at Week 104
Measure Description	A laboratory adverse experience (LAE) is defined as any unfavorable and unintended change in the chemistry of the body temporally associated with the use of the SPONSOR'S product, whether or not considered related to the use of the product.
Time Frame	Baseline to Week 104
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 who received at least 1 dose of the double-blind study therapy.

Reporting Groups

	Description
Sitagliptin 100 mg	The Sitagliptin 100 mg group includes data from patients randomized to receive treatment with 100 mg oral tablets of sitagliptin once daily.
Glipizide	The Glipizide group includes data from patients randomized to receive treatment with glipizide initiated at a dose of 1 tablet (5 mg) per day. Patients could then up-titrated to a total daily dose of 4 tablets twice daily (20mg/day) based on their glycemic control.

Measured Values

	Sitagliptin 100 mg	**Glipizide**
Number of Participants Analyzed [units: participants]	**588**	**584**
Number of Participants With Laboratory Adverse Experiences (LAEs) at Week 104 [units: Participants]		
With LAEs	**85**	**74**
Without LAEs	**503**	**510**

No statistical analysis provided for Number of Participants With Laboratory Adverse Experiences (LAEs) at Week 104

11. Secondary: Number of Participants With Serious LAEs at Week 104 [Time Frame: Baseline to Week 104]

Measure Type	Secondary
Measure Title	Number of Participants With Serious LAEs at Week 104
Measure Description	Serious LAEs are any LAEs occurring at any dose that: results in death; or is life threatening; or results in a persistent or significant disability/incapacity; or results in or prolongs an existing inpatient hospitalization; or is a congenital anomaly/birth defect; or is a cancer; or is an overdose.
Time Frame	Baseline to Week 104
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 who received at least 1 dose of the double-blind study therapy.

Reporting Groups

	Description
Sitagliptin 100 mg	The Sitagliptin 100 mg group includes data from patients randomized to receive treatment with 100 mg oral tablets of sitagliptin once daily.
Glipizide	The Glipizide group includes data from patients randomized to receive treatment with glipizide initiated at a dose of 1 tablet (5 mg) per day. Patients could then up-titrated to a total daily dose of 4 tablets twice daily (20mg/day) based on their glycemic control.

Measured Values

	Sitagliptin 100 mg	**Glipizide**
Number of Participants Analyzed [units: participants]	**588**	**584**
Number of Participants With Serious LAEs at Week 104 [units: Participants]		
With serious LAEs	**0**	**0**
Without serious LAEs	**588**	**584**

No statistical analysis provided for Number of Participants With Serious LAEs at Week 104

12. Secondary: Number of Participants With Drug-related LAEs at Week 104 [Time Frame: Baseline to Week 104]

Measure Type	Secondary
Measure Title	Number of Participants With Drug-related LAEs at Week 104
Measure Description	Participants with drug-related (as assessed by an investigator who is a qualified physician according to his/her best clinical judgment) LAEs.
Time Frame	Baseline to Week 104
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 who received at least 1 dose of the double-blind study therapy.

Reporting Groups

	Description
Sitagliptin 100 mg	The Sitagliptin 100 mg group includes data from patients randomized to receive treatment with 100 mg oral tablets of sitagliptin once daily.
Glipizide	The Glipizide group includes data from patients randomized to receive treatment with glipizide initiated at a dose of 1 tablet (5 mg) per day. Patients could then up-titrated to a total daily dose of 4 tablets twice daily (20mg/day) based on their glycemic control.

Measured Values

	Sitagliptin 100 mg	Glipizide
Number of Participants Analyzed [units: participants]	**588**	**584**
Number of Participants With Drug-related LAEs at Week 104 [units: Participants]	**18**	**21**

No statistical analysis provided for Number of Participants With Drug-related LAEs at Week 104

Serious Adverse Events

Hide Serious Adverse Events

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

Reporting Groups

	Description
Sitagliptin 100 mg	The Sitagliptin 100 mg group includes data from patients randomized to receive treatment with 100 mg oral tablets of sitagliptin once daily.
Glipizide	The Glipizide group includes data from patients randomized to receive treatment with glipizide initiated at a dose of 1 tablet (5 mg) per day. Patients could then up-titrated to a total daily dose of 4 tablets twice daily (20mg/day) based on their glycemic control.

Serious Adverse Events

	Sitagliptin 100 mg	Glipizide
Total, serious adverse events		
# participants affected / at risk	**64/588 (10.88%)**	**73/584 (12.50%)**
Blood and lymphatic system disorders		

Thrombocytopenia [*1]		
# participants affected / at risk	**1/588 (0.17%)**	**0/584 (0.00%)**
Cardiac disorders		
Acute Myocardial Infarction [*1]		
# participants affected / at risk	**0/588 (0.00%)**	**2/584 (0.34%)**
Angina Pectoris [*1]		
# participants affected / at risk	**1/588 (0.17%)**	**3/584 (0.51%)**
Angina Unstable [*1]		
# participants affected / at risk	**1/588 (0.17%)**	**0/584 (0.00%)**
Atrial Fibrillation [*1]		
# participants affected / at risk	**3/588 (0.51%)**	**0/584 (0.00%)**
Atrial Flutter [*1]		
# participants affected / at risk	**0/588 (0.00%)**	**1/584 (0.17%)**
Cardiac Failure Congestive [*1]		
# participants affected / at risk	**2/588 (0.34%)**	**1/584 (0.17%)**
Coronary Artery Disease [*1]		
# participants affected / at risk	**2/588 (0.34%)**	**0/584 (0.00%)**
Coronary Artery Occlusion [*1]		
# participants affected / at risk	**1/588 (0.17%)**	**0/584 (0.00%)**
Coronary Artery Stenosis [*1]		
# participants affected / at risk	**1/588 (0.17%)**	**0/584 (0.00%)**
Hypertensive Heart Disease [*1]		
# participants affected / at risk	**1/588 (0.17%)**	**1/584 (0.17%)**
Ischaemic Cardiomyopathy [*1]		
# participants affected / at risk	**1/588 (0.17%)**	**0/584 (0.00%)**
Myocardial Infarction [*1]		
# participants affected / at risk	**0/588 (0.00%)**	**2/584 (0.34%)**
Pericardial Effusion [*1]		
# participants affected / at risk	**0/588 (0.00%)**	**1/584 (0.17%)**
Sick Sinus Syndrome [*1]		
# participants affected / at risk	**0/588 (0.00%)**	**1/584 (0.17%)**
Supraventricular Tachycardia [*1]		
# participants affected / at risk	**2/588 (0.34%)**	**1/584 (0.17%)**
Ear and labyrinth disorders		
Sudden Hearing Loss [*1]		
# participants affected / at risk	**1/588 (0.17%)**	**0/584 (0.00%)**
Eye disorders		
Cataract [*1]		
# participants affected / at risk	**1/588 (0.17%)**	**0/584 (0.00%)**
Macular Hole [*1]		
# participants affected / at risk	**0/588 (0.00%)**	**1/584 (0.17%)**

Gastrointestinal disorders		
Abdominal Hernia [*1]		
# participants affected / at risk	**0/588 (0.00%)**	**1/584 (0.17%)**
Abdominal Pain [*1]		
# participants affected / at risk	**1/588 (0.17%)**	**0/584 (0.00%)**
Abdominal Strangulated Hernia [*1]		
# participants affected / at risk	**0/588 (0.00%)**	**1/584 (0.17%)**
Anal Fistula [*1]		
# participants affected / at risk	**0/588 (0.00%)**	**1/584 (0.17%)**
Diarrhoea [*1]		
# participants affected / at risk	**1/588 (0.17%)**	**0/584 (0.00%)**
Dyspepsia [*1]		
# participants affected / at risk	**1/588 (0.17%)**	**0/584 (0.00%)**
Enterocolitis [*1]		
# participants affected / at risk	**0/588 (0.00%)**	**1/584 (0.17%)**
Gastrointestinal Haemorrhage [*1]		
# participants affected / at risk	**1/588 (0.17%)**	**0/584 (0.00%)**
Inguinal Hernia [*1]		
# participants affected / at risk	**1/588 (0.17%)**	**1/584 (0.17%)**
Melaena [*1]		
# participants affected / at risk	**1/588 (0.17%)**	**0/584 (0.00%)**
Pancreatitis [*1]		
# participants affected / at risk	**1/588 (0.17%)**	**0/584 (0.00%)**
Rectal Polyp [*1]		
# participants affected / at risk	**1/588 (0.17%)**	**0/584 (0.00%)**
Splenic Artery Aneurysm [*1]		
# participants affected / at risk	**0/588 (0.00%)**	**1/584 (0.17%)**
Umbilical Hernia [*1]		
# participants affected / at risk	**1/588 (0.17%)**	**0/584 (0.00%)**
Upper Gastrointestinal Haemorrhage [*1]		
# participants affected / at risk	**0/588 (0.00%)**	**1/584 (0.17%)**
General disorders		
Chest Pain [*1]		
# participants affected / at risk	**0/588 (0.00%)**	**1/584 (0.17%)**
Fatigue [*1]		
# participants affected / at risk	**1/588 (0.17%)**	**0/584 (0.00%)**
Non-Cardiac Chest Pain [*1]		
# participants affected / at risk	**2/588 (0.34%)**	**2/584 (0.34%)**
Oedema Peripheral [*1]		
# participants affected / at risk	**1/588 (0.17%)**	**0/584 (0.00%)**
Polyserositis [*1]		

# participants affected / at risk	0/588 (0.00%)	1/584 (0.17%)
Pyrexia * 1		
# participants affected / at risk	1/588 (0.17%)	0/584 (0.00%)
Sudden Cardiac Death * 1		
# participants affected / at risk	0/588 (0.00%)	1/584 (0.17%)
Hepatobiliary disorders		
Bile Duct Stone * 1		
# participants affected / at risk	1/588 (0.17%)	0/584 (0.00%)
Cholecystitis Acute * 1		
# participants affected / at risk	1/588 (0.17%)	0/584 (0.00%)
Cholecystitis Chronic * 1		
# participants affected / at risk	1/588 (0.17%)	0/584 (0.00%)
Cholelithiasis * 1		
# participants affected / at risk	4/588 (0.68%)	0/584 (0.00%)
Hydrocholecystis * 1		
# participants affected / at risk	1/588 (0.17%)	0/584 (0.00%)
Infections and infestations		
Abdominal Wall Abscess * 1		
# participants affected / at risk	0/588 (0.00%)	1/584 (0.17%)
Arthritis Bacterial * 1		
# participants affected / at risk	1/588 (0.17%)	0/584 (0.00%)
Carbuncle * 1		
# participants affected / at risk	0/588 (0.00%)	1/584 (0.17%)
Cellulitis * 1		
# participants affected / at risk	1/588 (0.17%)	2/584 (0.34%)
Dengue Fever * 1		
# participants affected / at risk	0/588 (0.00%)	1/584 (0.17%)
Diabetic Foot Infection * 1		
# participants affected / at risk	0/588 (0.00%)	1/584 (0.17%)
Gastroenteritis * 1		
# participants affected / at risk	1/588 (0.17%)	0/584 (0.00%)
Gastroenteritis Viral * 1		
# participants affected / at risk	0/588 (0.00%)	1/584 (0.17%)
Helicobacter Infection * 1		
# participants affected / at risk	0/588 (0.00%)	1/584 (0.17%)
Localised Infection * 1		
# participants affected / at risk	0/588 (0.00%)	1/584 (0.17%)
Lower Respiratory Tract Infection * 1		
# participants affected / at risk	0/588 (0.00%)	1/584 (0.17%)
Pneumonia * 1		
# participants affected / at risk	1/588 (0.17%)	3/584 (0.51%)

Pneumonia Streptococcal [*1]		
# participants affected / at risk	**0/588 (0.00%)**	**1/584 (0.17%)**
Postoperative Wound Infection [*1]		
# participants affected / at risk	**0/588 (0.00%)**	**1/584 (0.17%)**
Sepsis [*1]		
# participants affected / at risk	**0/588 (0.00%)**	**1/584 (0.17%)**
Viral Infection [*1]		
# participants affected / at risk	**0/588 (0.00%)**	**1/584 (0.17%)**
Injury, poisoning and procedural complications		
Ankle Fracture [*1]		
# participants affected / at risk	**0/588 (0.00%)**	**1/584 (0.17%)**
Burns Third Degree [*1]		
# participants affected / at risk	**0/588 (0.00%)**	**1/584 (0.17%)**
Fall [*1]		
# participants affected / at risk	**1/588 (0.17%)**	**0/584 (0.00%)**
Lower Limb Fracture [*1]		
# participants affected / at risk	**1/588 (0.17%)**	**1/584 (0.17%)**
Medical Device Complication [*1]		
# participants affected / at risk	**1/588 (0.17%)**	**0/584 (0.00%)**
Meniscus Lesion [*1]		
# participants affected / at risk	**1/588 (0.17%)**	**2/584 (0.34%)**
Multiple Injuries [*1]		
# participants affected / at risk	**2/588 (0.34%)**	**0/584 (0.00%)**
Postoperative Thrombosis [*1]		
# participants affected / at risk	**0/588 (0.00%)**	**1/584 (0.17%)**
Procedural Complication [*1]		
# participants affected / at risk	**1/588 (0.17%)**	**0/584 (0.00%)**
Radius Fracture [*1]		
# participants affected / at risk	**1/588 (0.17%)**	**1/584 (0.17%)**
Tendon Injury [*1]		
# participants affected / at risk	**1/588 (0.17%)**	**0/584 (0.00%)**
Tendon Rupture [*1]		
# participants affected / at risk	**0/588 (0.00%)**	**1/584 (0.17%)**
Tibia Fracture [*1]		
# participants affected / at risk	**1/588 (0.17%)**	**0/584 (0.00%)**
Wound [*1]		
# participants affected / at risk	**0/588 (0.00%)**	**1/584 (0.17%)**
Investigations		
Intraocular Pressure Increased [*1]		
# participants affected / at risk	**0/588 (0.00%)**	**1/584 (0.17%)**
Metabolism and nutrition disorders		

Diabetic Foot [*1]		
# participants affected / at risk	**0/588 (0.00%)**	**1/584 (0.17%)**
Hyperglycaemia [*1]		
# participants affected / at risk	**1/588 (0.17%)**	**0/584 (0.00%)**
Obesity [*1]		
# participants affected / at risk	**0/588 (0.00%)**	**1/584 (0.17%)**
Musculoskeletal and connective tissue disorders		
Arthralgia [*1]		
# participants affected / at risk	**0/588 (0.00%)**	**2/584 (0.34%)**
Arthritis [*1]		
# participants affected / at risk	**0/588 (0.00%)**	**1/584 (0.17%)**
Intervertebral Disc Disorder [*1]		
# participants affected / at risk	**0/588 (0.00%)**	**1/584 (0.17%)**
Intervertebral Disc Protrusion [*1]		
# participants affected / at risk	**0/588 (0.00%)**	**2/584 (0.34%)**
Lumbar Spinal Stenosis [*1]		
# participants affected / at risk	**0/588 (0.00%)**	**2/584 (0.34%)**
Muscle Haemorrhage [*1]		
# participants affected / at risk	**1/588 (0.17%)**	**0/584 (0.00%)**
Musculoskeletal Pain [*1]		
# participants affected / at risk	**1/588 (0.17%)**	**0/584 (0.00%)**
Osteoarthritis [*1]		
# participants affected / at risk	**2/588 (0.34%)**	**0/584 (0.00%)**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Astrocytoma Malignant [*1]		
# participants affected / at risk	**0/588 (0.00%)**	**1/584 (0.17%)**
Basal Cell Carcinoma [*1]		
# participants affected / at risk	**1/588 (0.17%)**	**3/584 (0.51%)**
Bladder Cancer [*1]		
# participants affected / at risk	**1/588 (0.17%)**	**0/584 (0.00%)**
Bladder Transitional Cell Carcinoma [*1]		
# participants affected / at risk	**1/588 (0.17%)**	**0/584 (0.00%)**
Breast Cancer [*1]		
# participants affected / at risk	**0/588 (0.00%)**	**2/584 (0.34%)**
Carcinoid Tumour Of The Small Bowel [*1]		
# participants affected / at risk	**0/588 (0.00%)**	**1/584 (0.17%)**
Colon Cancer [*1]		
# participants affected / at risk	**1/588 (0.17%)**	**0/584 (0.00%)**
Diffuse Large B-Cell Lymphoma [*1]		
# participants affected / at risk	**1/588 (0.17%)**	**0/584 (0.00%)**
Gastric Cancer [*1]		

# participants affected / at risk	1/588 (0.17%)	0/584 (0.00%)
Hepatic Neoplasm Malignant Non-Resectable [*1]		
# participants affected / at risk	0/588 (0.00%)	1/584 (0.17%)
Malignant Melanoma [*1]		
# participants affected / at risk	0/588 (0.00%)	1/584 (0.17%)
Metastases To Bone [*1]		
# participants affected / at risk	1/588 (0.17%)	0/584 (0.00%)
Oesophageal Cancer Metastatic [*1]		
# participants affected / at risk	0/588 (0.00%)	1/584 (0.17%)
Prostate Cancer [*1]		
# participants affected / at risk	1/588 (0.17%)	2/584 (0.34%)
Rectal Cancer [*1]		
# participants affected / at risk	0/588 (0.00%)	1/584 (0.17%)
Renal Adenoma [*1]		
# participants affected / at risk	1/588 (0.17%)	0/584 (0.00%)
Renal Cell Carcinoma Stage Unspecified [*1]		
# participants affected / at risk	1/588 (0.17%)	1/584 (0.17%)
Squamous Cell Carcinoma Of Skin [*1]		
# participants affected / at risk	1/588 (0.17%)	0/584 (0.00%)
Uterine Leiomyoma [*1]		
# participants affected / at risk	1/588 (0.17%)	0/584 (0.00%)
Nervous system disorders		
Carotid Artery Stenosis [*1]		
# participants affected / at risk	0/588 (0.00%)	1/584 (0.17%)
Dizziness [*1]		
# participants affected / at risk	0/588 (0.00%)	1/584 (0.17%)
Guillain-Barre Syndrome [*1]		
# participants affected / at risk	0/588 (0.00%)	1/584 (0.17%)
Hemiparesis [*1]		
# participants affected / at risk	0/588 (0.00%)	1/584 (0.17%)
Lethargy [*1]		
# participants affected / at risk	0/588 (0.00%)	1/584 (0.17%)
Loss Of Consciousness [*1]		
# participants affected / at risk	0/588 (0.00%)	1/584 (0.17%)
Lumbar Radiculopathy [*1]		
# participants affected / at risk	2/588 (0.34%)	0/584 (0.00%)
Syncope [*1]		
# participants affected / at risk	0/588 (0.00%)	1/584 (0.17%)
Transient Ischaemic Attack [*1]		
# participants affected / at risk	0/588 (0.00%)	1/584 (0.17%)
Pregnancy, puerperium and perinatal conditions		

Abortion Spontaneous [*1]		
# participants affected / at risk	**0/588 (0.00%)**	**1/584 (0.17%)**
Psychiatric disorders		
Anxiety [*1]		
# participants affected / at risk	**0/588 (0.00%)**	**1/584 (0.17%)**
Completed Suicide [*1]		
# participants affected / at risk	**0/588 (0.00%)**	**1/584 (0.17%)**
Hallucination [*1]		
# participants affected / at risk	**0/588 (0.00%)**	**1/584 (0.17%)**
Renal and urinary disorders		
Calculus Ureteric [*1]		
# participants affected / at risk	**1/588 (0.17%)**	**0/584 (0.00%)**
Hydronephrosis [*1]		
# participants affected / at risk	**0/588 (0.00%)**	**1/584 (0.17%)**
Nephrolithiasis [*1]		
# participants affected / at risk	**1/588 (0.17%)**	**2/584 (0.34%)**
Renal Colic [*1]		
# participants affected / at risk	**1/588 (0.17%)**	**0/584 (0.00%)**
Renal Failure Acute [*1]		
# participants affected / at risk	**1/588 (0.17%)**	**0/584 (0.00%)**
Renal Mass [*1]		
# participants affected / at risk	**0/588 (0.00%)**	**1/584 (0.17%)**
Reproductive system and breast disorders		
Benign Prostatic Hyperplasia [*1]		
# participants affected / at risk	**1/588 (0.17%)**	**0/584 (0.00%)**
Vaginal Prolapse [*1]		
# participants affected / at risk	**1/588 (0.17%)**	**0/584 (0.00%)**
Respiratory, thoracic and mediastinal disorders		
Acute Pulmonary Oedema [*1]		
# participants affected / at risk	**1/588 (0.17%)**	**0/584 (0.00%)**
Asthma [*1]		
# participants affected / at risk	**1/588 (0.17%)**	**0/584 (0.00%)**
Dyspnoea [*1]		
# participants affected / at risk	**0/588 (0.00%)**	**1/584 (0.17%)**
Epistaxis [*1]		
# participants affected / at risk	**1/588 (0.17%)**	**0/584 (0.00%)**
Pickwickian Syndrome [*1]		
# participants affected / at risk	**0/588 (0.00%)**	**1/584 (0.17%)**
Pneumothorax [*1]		
# participants affected / at risk	**0/588 (0.00%)**	**1/584 (0.17%)**
Pulmonary Embolism [*1]		

# participants affected / at risk	0/588 (0.00%)	1/584 (0.17%)
Skin and subcutaneous tissue disorders		
Angioedema * 1		
# participants affected / at risk	0/588 (0.00%)	1/584 (0.17%)
Urticaria * 1		
# participants affected / at risk	1/588 (0.17%)	0/584 (0.00%)
Vascular disorders		
Deep Vein Thrombosis * 1		
# participants affected / at risk	0/588 (0.00%)	1/584 (0.17%)
Extremity Necrosis * 1		
# participants affected / at risk	0/588 (0.00%)	1/584 (0.17%)
Iliac Artery Stenosis * 1		
# participants affected / at risk	1/588 (0.17%)	0/584 (0.00%)
Peripheral Artery Aneurysm * 1		
# participants affected / at risk	1/588 (0.17%)	0/584 (0.00%)
Venous Insufficiency * 1		
# participants affected / at risk	1/588 (0.17%)	0/584 (0.00%)

* Events were collected by non-systematic assessment
1 Term from vocabulary, MedDRa Version 10.0

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 100 mg	The Sitagliptin 100 mg group includes data from patients randomized to receive treatment with 100 mg oral tablets of sitagliptin once daily.
Glipizide	The Glipizide group includes data from patients randomized to receive treatment with glipizide initiated at a dose of 1 tablet (5 mg) per day. Patients could then up-titrated to a total daily dose of 4 tablets twice daily (20mg/day) based on their glycemic control.

Other Adverse Events

	Sitagliptin 100 mg	Glipizide
Total, other (not including serious) adverse events		

# participants affected / at risk	318/588 (54.08%)	374/584 (64.04%)
Gastrointestinal disorders		
Diarrhoea * 1		
# participants affected / at risk	42/588 (7.14%)	40/584 (6.85%)
Infections and infestations		
Bronchitis * 1		
# participants affected / at risk	40/588 (6.80%)	37/584 (6.34%)
Influenza * 1		
# participants affected / at risk	32/588 (5.44%)	37/584 (6.34%)
Nasopharyngitis * 1		
# participants affected / at risk	71/588 (12.07%)	61/584 (10.45%)
Upper Respiratory Tract Infection * 1		
# participants affected / at risk	73/588 (12.41%)	79/584 (13.53%)
Urinary Tract Infection * 1		
# participants affected / at risk	44/588 (7.48%)	25/584 (4.28%)
Metabolism and nutrition disorders		
Hypoglycaemia * 1		
# participants affected / at risk	31/588 (5.27%)	199/584 (34.08%)
Musculoskeletal and connective tissue disorders		
Arthralgia * 1		
# participants affected / at risk	34/588 (5.78%)	32/584 (5.48%)
Back Pain * 1		
# participants affected / at risk	35/588 (5.95%)	32/584 (5.48%)
Nervous system disorders		
Headache * 1		
# participants affected / at risk	33/588 (5.61%)	35/584 (5.99%)
Respiratory, thoracic and mediastinal disorders		
Cough * 1		
# participants affected / at risk	23/588 (3.91%)	32/584 (5.48%)
Vascular disorders		
Hypertension * 1		
# participants affected / at risk	29/588 (4.93%)	31/584 (5.31%)

* Events were collected by non-systematic assessment

1 Term from vocabulary, MedDRa Version 10.0

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: Senior Vice President, Global Clinical Development
Organization: Merck Sharp & Dohme Corp
phone: 1-800-672-6372

Publications:

Nauck MA, Meininger G, Sheng D, Terranella L, Stein PP; Sitagliptin Study 024 Group. Efficacy and safety of the dipeptidyl peptidase-4 inhibitor, sitagliptin, compared with the sulfonylurea, glipizide, in patients with type 2 diabetes inadequately controlled on metformin alone: a randomized, double-blind, non-inferiority trial. Diabetes Obes Metab. 2007 Mar;9(2):194-205.

Publications automatically indexed to this study by ClinicalTrials.gov Identifier (NCT Number):

Seck TL, Engel SS, Williams-Herman DE, Sisk CM, Golm GT, Wang H, Kaufman KD, Goldstein BJ. Sitagliptin more effectively achieves a composite endpoint for A1C reduction, lack of hypoglycemia and no body weight gain compared with glipizide. Diabetes Res Clin Pract. 2011 Jul;93(1):e15-7. doi: 10.1016/j.diabres.2011.03.006. Epub 2011 Apr 8.

Seck T, Nauck M, Sheng D, Sunga S, Davies MJ, Stein PP, Kaufman KD, Amatruda JM; Sitagliptin Study 024 Group. Safety and efficacy of treatment with sitagliptin or glipizide in patients with type 2 diabetes inadequately controlled on metformin: a 2-year study. Int J Clin Pract. 2010 Apr;64(5):562-76. doi: 10.1111/j.1742-1241.2010.02353.x.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00094770 History of Changes
Other Study ID Numbers:	0431-024 MK0431-024 2004_049
Study First Received:	October 22, 2004
Results First Received:	September 24, 2009
Last Updated:	April 27, 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