# Study of Sitagliptin for the Treatment of Type 2 Diabetes Mellitus With Inadequate Glycemic Control on Insulin (MK-0431-260)

**This study has been completed.**

**Sponsor:**
Merck Sharp & Dohme Corp.

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

**ClinicalTrials.gov Identifier:**
NCT01462266

First received: October 27, 2011
Last updated: April 20, 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 study is to examine the insulin-sparing effect of sitagliptin 100 mg once-daily compared with placebo over 24 weeks in participants with type 2 diabetes mellitus who have inadequate glycemic control on insulin alone or in combination with metformin. The primary hypothesis of this study is that after 24 weeks, sitagliptin reduces the dose of insulin relative to placebo.

| Condition | Intervention | Phase |
|---|---|---|
| Type 2 Diabetes Mellitus | Drug: Sitagliptin<br>Drug: Comparator: Placebo<br>Biological: Insulin Glargine<br>Drug: Metformin | Phase 3 |

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

Official Title: A Phase III, Multicenter, Randomized, Double-Blind, Placebo-Controlled Clinical Trial to Study the Safety and Insulin-Sparing Efficacy of the Addition of Sitagliptin in Patients With Type 2 Diabetes Mellitus Who Have Inadequate Glycemic Control on Insulin Alone or in Combination With Metformin

**Resource links provided by NLM:**

MedlinePlus related topics: Diabetes Type 2

Drug Information available for: Metformin Metformin hydrochloride Insulin Insulin human Insulin glargine Sitagliptin Sitagliptin phosphate

U.S. FDA Resources

**Further study details as provided by Merck Sharp & Dohme Corp.:**

Primary Outcome Measures:

- Change From Baseline in Daily Insulin Dose at Week 24 [ Time Frame: Baseline and Week 24 ] [ Designated as safety issue: No ]

  Change in daily insulin dose following 24 weeks of therapy (i.e., daily insulin dose at Week 24 minus daily insulin dose at baseline)

Secondary Outcome Measures:

- Change From Baseline in Hemoglobin A1c (A1C) at Week 24 [ Time Frame: Baseline and Week 24 ] [ Designated as safety issue: No ]

  A1C is measured as the percentage of glycosylated hemoglobin. Change in A1C following 24 weeks of therapy (i.e., A1C at Week 24 minus A1C at baseline)

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

  Change in FPG (before breakfast) following 24 weeks of therapy (i.e., FPG at Week 24 minus FPG at baseline)

- Percent of Participants Achieving Fasting Glucose Target at Any Time During the Study [ Time Frame: Up to 24 weeks ] [ Designated as safety issue: No ]

  The fasting glucose target was defined as 3 consecutive days with a fingerstick glucose of 72 to 100 mg/dL (4.0 - 5.6 mmol/L).

- Time to Achieve the Fasting Glucose Target [ Time Frame: Up to 24 weeks ] [ Designated as safety issue: No ]

  Fasting glucose target 3 consecutive days with a fingerstick glucose of 72 to 100 mg/dL (4.0 - 5.6 mmol/L). This analysis was the Kaplan-Meier estimated 50th percentile of time (days) to first attainment of target.

| | |
|---|---|
| Enrollment: | 660 |
| Study Start Date: | January 2012 |
| Study Completion Date: | June 2013 |
| Primary Completion Date: | June 2013 (Final data collection date for primary outcome measure) |

| Arms | Assigned Interventions |
|---|---|
| Experimental: Sitagliptin<br>Sitagliptin 100 mg once daily | Drug: Sitagliptin<br>Sitagliptin 100 mg tablet once daily for 24 weeks<br>Other Name: Januvia<br>Biological: Insulin Glargine<br>Participants on insulin glargine or another insulin regimen for at least 10 weeks prior to screening will continue or switch to open-label insulin glargine once-daily in the evening for the duration of the study.<br>Drug: Metformin<br>Participants on metformin oral tablet(s) at a dose of at least 1500 mg/day for at least 10 weeks prior to screening will continue receiving metformin at their current dose for the duration of the study.<br>Other Name: Glucophage |
| Placebo Comparator: Placebo<br>Placebo to sitagliptin once daily | Drug: Comparator: Placebo<br>Placebo to sitagliptin once daily for 24 weeks<br>Biological: Insulin Glargine<br>Participants on insulin glargine or another insulin regimen for at least 10 weeks prior to screening will continue or switch to open-label insulin glargine once-daily in the evening for the duration of the study.<br>Drug: Metformin<br>Participants on metformin oral tablet(s) at a dose of at least 1500 mg/day for at least 10 weeks prior to screening will continue receiving metformin at their current dose for the duration of the study.<br>Other Name: Glucophage |

## Eligibility

Ages Eligible for Study: 18 Years to 80 Years
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

**Criteria**

Inclusion Criteria:

- has type 2 diabetes mellitus
- has one of the following criteria:
  - diagnosed with diabetes after age 40 years and insulin therapy was initiated at least 3 years following diagnosis
  - if diagnosed with diabetes under age 40 years or insulin started earlier than 3 years after diagnosis, has a fasting C-peptide greater than 0.7 ng/mL
- must be at least 18 years of age and less than or equal to 80 years of age (for participants in India: must be at least 18 years of age and less than or equal to 65 years of age)
- on a stable regimen of insulin for at least 10 weeks with or without metformin (at least 1500 mg/day) and/or sulfonylurea for at least 10 weeks
- is highly unlikely to become pregnant (not of reproductive potential or agrees to remain abstinent or use (or have their partner use) an acceptable method of birth control during the study and for 14 days after the last dose of study medication

Exclusion Criteria:

- has been treated with a dipeptidyl peptidase IV (DPP-4) inhibitor, a thiazolidinedione (TZD), or a glucagon-like peptide-1 (GLP-1) mimetic or analogue, within the past 12 weeks
- currently on treatment with daily use (one or more injections per day) of a

pre-prandial short-acting or rapid-acting insulin alone or as part of a basal/bolus insulin regimen

- has symptomatic hyperglycemia that requires immediate initiation, adjustment, or addition of antihyperglycemic therapy
- has a history of 2 or more episodes of hypoglycemia resulting in seizure,

coma, or loss of consciousness, - or - has had recurrent (≥3 times per week) episodes of hypoglycemia over the past 8 weeks

- has a history of ketoacidosis
- is not appropriate for or does not agree to target a fasting glucose of 72-100 mg/dL [4.0-5.6 mmol/L]
- is on or likely to require treatment with corticosteroids
- has undergone a surgical procedure within 4 weeks or has planned major surgery during the study
- is currently being treated for hyperthyroidism or is on thyroid hormone

therapy and has not been on a stable dose for at least 6 weeks

- has a history of active liver disease (other than non-alcoholic hepatic

steatosis)

- has had new or worsening signs or symptoms of coronary heart disease or

congestive heart failure within the past 3 months, or has any of the following

disorders within the past 3 months:

- acute coronary syndrome
- coronary artery intervention
- stroke or transient ischemic neurological disorder
  - has a systolic blood pressure greater than 160 mm Hg or a diastolic blood pressure greater than 90 mm Hg
  - has human immunodeficiency virus (HIV)
  - has severe peripheral vascular disease
  - has a clinically important hematological disorder
  - has a history of malignancy that is less than 5 years from study start, except for adequately treated basal cell or squamous cell skin cancer or in situ cervical cancer
  - has a positive urine pregnancy test
  - is pregnant or breast-feeding, or is expecting to conceive or donate eggs

during the study

- a user of recreational or illicit drugs or has had a recent history of drug abuse

## 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:

Mathieu C, Shankar RR, Lorber D, Umpierrez G, Wu F, Xu L, Golm GT, Latham M, Kaufman KD, Engel SS. A Randomized Clinical Trial to Evaluate the Efficacy and Safety of Co-Administration of Sitagliptin with Intensively Titrated Insulin Glargine. Diabetes Ther. 2015 Jun;6(2):127-42. doi: 10.1007/s13300-015-0105-3. Epub 2015 Mar 28.

| | |
|---|---|
| Responsible Party: | Merck Sharp & Dohme Corp. |
| ClinicalTrials.gov Identifier: | NCT01462266 History of Changes |
| Other Study ID Numbers: | 0431-260 |
| Study First Received: | October 27, 2011 |
| Results First Received: | January 8, 2014 |
| Last Updated: | April 20, 2015 |
| Health Authority: | United States: Food and Drug Administration |

Additional relevant MeSH terms:

| | |
|---|---|
| Diabetes Mellitus | Enzyme Inhibitors |
| Diabetes Mellitus, Type 2 | Hormones |
| Endocrine System Diseases | Hormones, Hormone Substitutes, and Hormone Antagonists |
| Glucose Metabolism Disorders | Hypoglycemic Agents |
| Metabolic Diseases | Incretins |
| Glargine | Molecular Mechanisms of Pharmacological Action |
| Insulin | Pharmacologic Actions |
| Metformin | Physiological Effects of Drugs |
| Sitagliptin | Protease Inhibitors |
| Dipeptidyl-Peptidase IV Inhibitors | |

ClinicalTrials.gov processed this record on April 13, 2016

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Results First Received: January 8, 2014

| | |
|---|---|
| **Study Type:** | Interventional |
| **Study Design:** | Allocation: Randomized; Endpoint Classification: Efficacy Study;<br>Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Investigator);<br>Primary Purpose: Treatment |
| **Condition:** | Type 2 Diabetes Mellitus |
| **Interventions:** | Drug: Sitagliptin<br>Drug: Comparator: Placebo<br>Biological: Insulin Glargine<br>Drug: Metformin |

## 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** | Sitagliptin 100 mg administered orally once daily for 24 weeks. |
| **Placebo** | Placebo to sitagliptin administered orally once daily for 24 weeks. |

**Participant Flow: Overall Study**

| | Sitagliptin | Placebo |
|---|---|---|
| **STARTED** | **330** | **330** |
| **Treated** | **329** [1] | **329** [1] |
| **COMPLETED** | **295** | **303** |
| **NOT COMPLETED** | **35** | **27** |
| **Adverse Event** | **7** | **6** |
| **Death** | **2** | **1** |
| **Lack of Efficacy** | **0** | **2** |
| **Lost to Follow-up** | **4** | **3** |
| **Non-compliance with study drug** | **3** | **0** |
| **Creatinine and eGFR, excluded medication** | **8** | **4** |
| **Physician Decision** | **2** | **5** |
| **Protocol Violation** | **1** | **3** |
| **Withdrawal by Subject** | **7** | **2** |
| **Screen failure** | **1** | **1** |

[1] One participant was randomized in error and did not receive study medication.

## 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.** |
|---|
| One participant in both the Sitagliptin group and Placebo group was randomized in error and did not receive study medication. |

**Reporting Groups**

| | Description |
|---|---|

| | |
|---|---|
| **Sitagliptin** | Sitagliptin 100 mg administered orally once daily for 24 weeks. |
| **Placebo** | Placebo to sitagliptin administered orally once daily for 24 weeks. |
| **Total** | Total of all reporting groups |

**Baseline Measures**

| | Sitagliptin | Placebo | Total |
|---|---|---|---|
| **Number of Participants [units: participants]** | **329** | **329** | **658** |
| **Age [units: Years] Mean (Standard Deviation)** | **59.3 (8.9)** | **58.3 (9.7)** | **58.8 (9.3)** |
| **Gender [units: Participants]** | | | |
| **Female** | **178** | **165** | **343** |
| **Male** | **151** | **164** | **315** |

## Outcome Measures

Hide All Outcome Measures

1. Primary: Change From Baseline in Daily Insulin Dose at Week 24 [ Time Frame: Baseline and Week 24 ]

| | |
|---|---|
| **Measure Type** | Primary |
| **Measure Title** | Change From Baseline in Daily Insulin Dose at Week 24 |
| **Measure Description** | Change in daily insulin dose following 24 weeks of therapy (i.e., daily insulin dose at Week 24 minus daily insulin dose at baseline) |
| **Time Frame** | Baseline and Week 24 |
| **Safety Issue** | No |

**Population Description**

| **Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.** |
|---|
| Full Analysis Set (FAS) population included all randomized participants who took at least one dose of study medication and had at least one measurement either at baseline or post-randomization. |

**Reporting Groups**

| | Description |
|---|---|
| **Sitagliptin** | Sitagliptin 100 mg administered orally once daily for 24 weeks. |
| **Placebo** | Placebo to sitagliptin administered orally once daily for 24 weeks. |

**Measured Values**

| | Sitagliptin | Placebo |
|---|---|---|
| **Number of Participants Analyzed** | | |

| | | |
|---|---|---|
| **[units: participants]** | **329** | **329** |
| **Change From Baseline in Daily Insulin Dose at Week 24**<br><br>**[units: International Units (IU)]**<br>**Least Squares Mean (95% Confidence Interval)** | **19.0 (16.5 to 21.6)** | **23.8 (21.3 to 26.3)** |

**Statistical Analysis 1 for Change From Baseline in Daily Insulin Dose at Week 24**

| | |
|---|---|
| **Groups** [1] | All groups |
| **Method** [2] | Longitudinal data analysis |
| **P Value** [3] | 0.009 |
| **Mean Difference (Final Values)** [4] | -4.7 |
| **95% Confidence Interval** | -8.3 to -1.2 |

| | |
|---|---|
| **[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: |
| | Adjusting for participant's use of metformin at Visit 1/Screening Visit (i.e., on metformin, or not on metformin) |
| **[3]** | Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance: |
| | No text entered. |
| **[4]** | Other relevant estimation information: |
| | No text entered. |

2. Secondary: Change From Baseline in Hemoglobin A1c (A1C) at Week 24 [ Time Frame: Baseline and Week 24 ]

| | |
|---|---|
| **Measure Type** | Secondary |
| **Measure Title** | Change From Baseline in Hemoglobin A1c (A1C) at Week 24 |
| **Measure Description** | A1C is measured as the percentage of glycosylated hemoglobin. Change in A1C following 24 weeks of therapy (i.e., A1C at Week 24 minus A1C at baseline) |
| **Time Frame** | Baseline and Week 24 |
| **Safety Issue** | No |

**Population Description**

| **Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.** |
|---|
| FAS population included all randomized participants who took at least one dose of study medication and had at least one measurement either at baseline or post-randomization. |

**Reporting Groups**

| | **Description** |
|---|---|
| **Sitagliptin** | Sitagliptin 100 mg administered orally once daily for 24 weeks. |

| | |
|---|---|
| **Placebo** | Placebo to sitagliptin administered orally once daily for 24 weeks. |

**Measured Values**

| | Sitagliptin | Placebo |
|---|---|---|
| **Number of Participants Analyzed [units: participants]** | **329** | **329** |
| **Change From Baseline in Hemoglobin A1c (A1C) at Week 24 [units: Percent of total hemoglobin] Least Squares Mean (95% Confidence Interval)** | **-1.31 (-1.43 to -1.20)** | **-0.87 (-0.98 to -0.75)** |

**No statistical analysis provided for Change From Baseline in Hemoglobin A1c (A1C) at Week 24**

3. Secondary: Change From Baseline in Fasting Plasma Glucose (FPG) at Week 24 [ Time Frame: Baseline and Week 24 ]

| | |
|---|---|
| **Measure Type** | Secondary |
| **Measure Title** | Change From Baseline in Fasting Plasma Glucose (FPG) at Week 24 |
| **Measure Description** | Change in FPG (before breakfast) following 24 weeks of therapy (i.e., FPG at Week 24 minus FPG at baseline) |
| **Time Frame** | Baseline and Week 24 |
| **Safety Issue** | No |

**Population Description**

| **Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.** |
|---|
| FAS population included all randomized participants who took at least one dose of study medication and had at least one measurement either at baseline or post-randomization. |

**Reporting Groups**

| | Description |
|---|---|
| **Sitagliptin** | Sitagliptin 100 mg administered orally once daily for 24 weeks. |
| **Placebo** | Placebo to sitagliptin administered orally once daily for 24 weeks. |

**Measured Values**

| | Sitagliptin | Placebo |
|---|---|---|
| **Number of Participants Analyzed [units: participants]** | **329** | **329** |
| **Change From Baseline in Fasting Plasma Glucose (FPG) at Week 24 [units: mg/dL] Least Squares Mean (95% Confidence Interval)** | **-55.5 (-61.1 to -49.9)** | **-44.8 (-50.4 to -39.2)** |

**No statistical analysis provided for Change From Baseline in Fasting Plasma Glucose (FPG) at Week 24**

4. Secondary: Percent of Participants Achieving Fasting Glucose Target at Any Time During the Study [ Time Frame: Up to 24 weeks ]

| | |
|---|---|
| **Measure Type** | Secondary |
| **Measure Title** | Percent of Participants Achieving Fasting Glucose Target at Any Time During the Study |
| **Measure Description** | The fasting glucose target was defined as 3 consecutive days with a fingerstick glucose of 72 to 100 mg/dL (4.0 - 5.6 mmol/L). |
| **Time Frame** | Up to 24 weeks |
| **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.** |
|---|
| FAS population included all randomized participants who took at least one dose of study medication, and had at least one post-randomization glycemic goal assessment. |

**Reporting Groups**

| | **Description** |
|---|---|
| **Sitagliptin** | Sitagliptin 100 mg administered orally once daily for 24 weeks. |
| **Placebo** | Placebo to sitagliptin administered orally once daily for 24 weeks. |

**Measured Values**

| | **Sitagliptin** | **Placebo** |
|---|---|---|
| **Number of Participants Analyzed [units: participants]** | **327** | **326** |
| **Percent of Participants Achieving Fasting Glucose Target at Any Time During the Study [units: Percentage of participants] Number (95% Confidence Interval)** | **77.4 (72.6 to 82.2)** | **74.1 (69.0 to 79.2)** |

**No statistical analysis provided for Percent of Participants Achieving Fasting Glucose Target at Any Time During the Study**

5. Secondary: Time to Achieve the Fasting Glucose Target [ Time Frame: Up to 24 weeks ]

| | |
|---|---|
| **Measure Type** | Secondary |
| **Measure Title** | Time to Achieve the Fasting Glucose Target |
| **Measure Description** | Fasting glucose target 3 consecutive days with a fingerstick glucose of 72 to 100 mg/dL (4.0 - 5.6 mmol/L). This analysis was the Kaplan-Meier estimated 50th percentile of time (days) to first attainment of target. |
| **Time Frame** | Up to 24 weeks |
| **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.** |
|---|

FAS population included all randomized participants who took at least one dose of study medication and had at least one post-randomization glycemic goal assessment.

**Reporting Groups**

| | Description |
|---|---|
| **Sitagliptin** | Sitagliptin 100 mg administered orally once daily for 24 weeks. |
| **Placebo** | Placebo to sitagliptin administered orally once daily for 24 weeks. |

**Measured Values**

| | Sitagliptin | Placebo |
|---|---|---|
| **Number of Participants Analyzed [units: participants]** | **253** | **242** |
| **Time to Achieve the Fasting Glucose Target [units: Days to first attainment of target] Median (95% Confidence Interval)** | **78 (64 to 85)** | **90 (80 to 107)** |

**No statistical analysis provided for Time to Achieve the Fasting Glucose Target**

## Serious Adverse Events

Hide Serious Adverse Events

| | |
|---|---|
| **Time Frame** | Up to Week 24 + 14-day follow-up |
| **Additional Description** | No text entered. |

**Reporting Groups**

| | Description |
|---|---|
| **Sitagliptin** | Sitagliptin 100 mg administered orally once daily for 24 weeks. |
| **Placebo** | Placebo to sitagliptin administered orally once daily for 24 weeks. |

**Serious Adverse Events**

| | Sitagliptin | Placebo |
|---|---|---|
| **Total, serious adverse events** | | |
| **# participants affected / at risk** | **13/329 (3.95%)** | **12/329 (3.65%)** |
| **Blood and lymphatic system disorders** | | |
| **Thrombocytopenia † 1** | | |
| **# participants affected / at risk** | **0/329 (0.00%)** | **1/329 (0.30%)** |
| **# events** | **0** | **1** |
| **Cardiac disorders** | | |
| **Acute coronary syndrome † 1** | | |

| | | |
|---|---|---|
| # participants affected / at risk | 0/329 (0.00%) | 1/329 (0.30%) |
| # events | 0 | 1 |
| Acute myocardial infarction † 1 | | |
| # participants affected / at risk | 0/329 (0.00%) | 1/329 (0.30%) |
| # events | 0 | 1 |
| Angina pectoris † 1 | | |
| # participants affected / at risk | 0/329 (0.00%) | 1/329 (0.30%) |
| # events | 0 | 1 |
| Coronary artery disease † 1 | | |
| # participants affected / at risk | 1/329 (0.30%) | 0/329 (0.00%) |
| # events | 1 | 0 |
| Myocardial infarction † 1 | | |
| # participants affected / at risk | 1/329 (0.30%) | 1/329 (0.30%) |
| # events | 1 | 1 |
| General disorders | | |
| Chest pain † 1 | | |
| # participants affected / at risk | 1/329 (0.30%) | 0/329 (0.00%) |
| # events | 1 | 0 |
| Immune system disorders | | |
| Hypersensitivity † 1 | | |
| # participants affected / at risk | 0/329 (0.00%) | 1/329 (0.30%) |
| # events | 0 | 1 |
| Infections and infestations | | |
| Appendicitis perforated † 1 | | |
| # participants affected / at risk | 1/329 (0.30%) | 0/329 (0.00%) |
| # events | 1 | 0 |
| Cellulitis † 1 | | |
| # participants affected / at risk | 1/329 (0.30%) | 1/329 (0.30%) |
| # events | 1 | 2 |
| Gastroenteritis † 1 | | |
| # participants affected / at risk | 0/329 (0.00%) | 1/329 (0.30%) |
| # events | 0 | 1 |
| Herpes zoster † 1 | | |
| # participants affected / at risk | 0/329 (0.00%) | 1/329 (0.30%) |
| # events | 0 | 1 |
| Pneumonia † 1 | | |
| # participants affected / at risk | 0/329 (0.00%) | 1/329 (0.30%) |
| # events | 0 | 1 |
| Sepsis † 1 | | |
| # participants affected / at risk | 0/329 (0.00%) | 1/329 (0.30%) |
| # events | 0 | 1 |
| Subcutaneous abscess † 1 | | |
| # participants affected / at risk | 1/329 (0.30%) | 0/329 (0.00%) |
| # events | 1 | 0 |
| Tuberculosis † 1 | | |

| | | |
|---|---|---|
| # participants affected / at risk | 0/329 (0.00%) | 1/329 (0.30%) |
| # events | 0 | 1 |
| **Injury, poisoning and procedural complications** | | |
| Contusion † 1 | | |
| # participants affected / at risk | 1/329 (0.30%) | 0/329 (0.00%) |
| # events | 1 | 0 |
| Foot fracture † 1 | | |
| # participants affected / at risk | 0/329 (0.00%) | 1/329 (0.30%) |
| # events | 0 | 1 |
| Overdose † 1 | | |
| # participants affected / at risk | 1/329 (0.30%) | 0/329 (0.00%) |
| # events | 1 | 0 |
| Tendon rupture † 1 | | |
| # participants affected / at risk | 0/329 (0.00%) | 1/329 (0.30%) |
| # events | 0 | 1 |
| **Musculoskeletal and connective tissue disorders** | | |
| Monarthritis † 1 | | |
| # participants affected / at risk | 1/329 (0.30%) | 0/329 (0.00%) |
| # events | 1 | 0 |
| **Nervous system disorders** | | |
| Hemiparesis † 1 | | |
| # participants affected / at risk | 1/329 (0.30%) | 0/329 (0.00%) |
| # events | 1 | 0 |
| **Reproductive system and breast disorders** | | |
| Spermatocele † 1 | | |
| # participants affected / at risk | 1/329 (0.30%) | 0/329 (0.00%) |
| # events | 1 | 0 |
| **Respiratory, thoracic and mediastinal disorders** | | |
| Status asthmaticus † 1 | | |
| # participants affected / at risk | 1/329 (0.30%) | 0/329 (0.00%) |
| # events | 1 | 0 |
| **Skin and subcutaneous tissue disorders** | | |
| Ingrowing nail † 1 | | |
| # participants affected / at risk | 1/329 (0.30%) | 0/329 (0.00%) |
| # events | 1 | 0 |
| **Vascular disorders** | | |
| Hypertensive crisis † 1 | | |
| # participants affected / at risk | 1/329 (0.30%) | 0/329 (0.00%) |
| # events | 1 | 0 |

† Events were collected by systematic assessment

1 Term from vocabulary, MedDRA 16.0

## Other Adverse Events

Hide Other Adverse Events

| | |
|---|---|
| **Time Frame** | Up to Week 24 + 14-day follow-up |
| **Additional Description** | No text entered. |

**Frequency Threshold**

| | |
|---|---|
| **Threshold above which other adverse events are reported** | 5% |

**Reporting Groups**

| | Description |
|---|---|
| **Sitagliptin** | Sitagliptin 100 mg administered orally once daily for 24 weeks. |
| **Placebo** | Placebo to sitagliptin administered orally once daily for 24 weeks. |

**Other Adverse Events**

| | Sitagliptin | Placebo |
|---|---|---|
| **Total, other (not including serious) adverse events** | | |
| **# participants affected / at risk** | **121/329 (36.78%)** | **168/329 (51.06%)** |
| **Gastrointestinal disorders** | | |
| **Diarrhoea † 1** | | |
| **# participants affected / at risk** | **17/329 (5.17%)** | **11/329 (3.34%)** |
| **# events** | **19** | **11** |
| **Infections and infestations** | | |
| **Nasopharyngitis † 1** | | |
| **# participants affected / at risk** | **13/329 (3.95%)** | **26/329 (7.90%)** |
| **# events** | **16** | **29** |
| **Urinary tract infection † 1** | | |
| **# participants affected / at risk** | **14/329 (4.26%)** | **17/329 (5.17%)** |
| **# events** | **16** | **18** |
| **Metabolism and nutrition disorders** | | |
| **Hypoglycaemia † 1** | | |
| **# participants affected / at risk** | **93/329 (28.27%)** | **144/329 (43.77%)** |
| **# events** | **358** | **794** |

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA 16.0

## 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:** 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:**

Mathieu C, Shankar RR, Lorber D, Umpierrez G, Wu F, Xu L, Golm GT, Latham M, Kaufman KD, Engel SS. A Randomized Clinical Trial to Evaluate the Efficacy and Safety of Co-Administration of Sitagliptin with Intensively Titrated Insulin Glargine. Diabetes Ther. 2015 Jun;6(2):127-42. doi: 10.1007/s13300-015-0105-3. Epub 2015 Mar 28.

| | |
|---|---|
| Responsible Party: | Merck Sharp & Dohme Corp. |
| ClinicalTrials.gov Identifier: | NCT01462266 History of Changes |
| Other Study ID Numbers: | 0431-260 |
| Study First Received: | October 27, 2011 |
| Results First Received: | January 8, 2014 |
| Last Updated: | April 20, 2015 |
| Health Authority: | United States: Food and Drug Administration |

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