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Safety and Efficacy of Sitagliptin Compared With Glimepiride in Elderly Participants With Type 2 Diabetes Mellitus (MK-0431-251)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

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

ClinicalTrials.gov Identifier:
NCT01189890

First received: August 25, 2010
Last updated: June 30, 2015
Last verified: June 2015
History of Changes

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Purpose

The primary objectives of this study are to determine if sitagliptin treatment is not inferior to that of glimepiride as measured by the change in baseline hemoglobin A1C (HbA1C) after 30 weeks of treatment, and if sitagliptin treatment results in a lower incidence of symptomatic hypoglycemia compared to that of glimepiride. The study will also evaluate if sitagliptin treatment, compared to glimepiride results in improvements in fasting plasma glucose (FPG) levels, and plasma lipid levels after 30 weeks of treatment. Participants will be randomized to either sitagliptin or glimepiride treatment after eligibility for study participation is determined during screening and washout study phases. Participants and study staff will not know to which treatment group they have been randomized (double-blind design). The duration of study participation will be up to 40 weeks (with 9 clinic visits). This will include a screening phase (Visit 1 to Visit 2) of 2 weeks maximum; a 6-week (Visits 2 to 3) oral antihyperglycemic agent (AHA) wash-out phase (for those who have been taking a AHA prior to the study); a placebo run-in phase (Visits 3 to 4), followed by up to 30 weeks of treatment with study medication.

Condition	Intervention	Phase
Type 2 Diabetes Mellitus	Drug: sitagliptin phosphate Drug: Glimepiride Drug: Placebo to Sitagliptin Drug: Placebo to Glimepiride	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 Phase III, Multicenter, Double-Blind, Randomized, Active-Controlled Study to Evaluate the Safety and Efficacy of Sitagliptin Compared With Glimepiride in Elderly Patients With Type 2 Diabetes Mellitus With Inadequate Glycemic Control

Resource links provided by NLM:

MedlinePlus related topics: Diabetes Type 2

Drug Information available for: Glimepiride Sitagliptin Sitagliptin phosphate

U.S. FDA Resources

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

Primary Outcome Measures:

- Least Squares (LS) Mean Change From Baseline in Hemoglobin A1c (HbA1c) at Week 30 [Time Frame: Baseline and Week 30] [Designated as safety issue: No]

  Participant whole blood samples were collected at baseline and Week 30 to determine the LS mean HbA1c change from baseline. HbA1c is a measure of the percentage of glycated hemoglobin in the blood and provides an indication of participant blood glucose control in the 2 to 3 months prior to the evaluation.

- Number of Participants With an Adverse Event of Symptomatic Hypoglycemia Up to Week 30 [Time Frame: Up to Week 30] [Designated as safety issue: Yes]

  Symptomatic hypoglycemia was defined as an episode with clinical symptoms attributed to hypoglycemia, without regard to glucose level. Participants were instructed to complete the Hypoglycemia Assessment Log (HAL) for any symptomatic episodes he or she believed represent hypoglycemia. If a fingerstick glucose was obtained before or shortly (i.e., within a few minutes) after treating, the value was recorded in the HAL. In addition, participants were instructed to record in the HAL any fingerstick glucose values ≤70 mg/dL (≤3.9 mmol/L) regardless of the presence of clinical symptoms.

- Number of Participants Experiencing An Adverse Event (AE) [Time Frame: Up to Week 30] [Designated as safety issue: Yes]

  An AE was defined as any unfavorable and unintended change in the structure, function, or chemistry of the body temporally associated with the use of the study treatment, whether or not considered related to the use of the treatment administered.

- Number of Participants Discontinuing Study Treatment Due to An AE [Time Frame: Up to Week 30] [Designated as safety issue: Yes]

  An AE was defined as any unfavorable and unintended change in the structure, function, or chemistry of the body temporally associated with the use of the study treatment, whether or not considered related to the use of the treatment administered.

Secondary Outcome Measures:

- LS Mean Change From Baseline in Fasting Plasma Glucose (FPG) at Week 30 [Time Frame: Baseline and Week 30] [Designated as safety issue: No]

  Plasma samples were collected from participants after an overnight fast at baseline and Week 30 to determine the mean change from baseline in participant FPG.

- Percentage of Participants With HbA1c <7.0% at Week 30 [Time Frame: Week 30] [Designated as safety issue: No]

  Participant whole blood samples were collected at Week 30 to determine the number of participants achieving HbA1c <7.0% at Week 30. HbA1c is a measure of the percentage of glycated hemoglobin in the blood and provides an indication of participant blood glucose control in the 2 to 3 months prior to the evaluation.

- Percentage of Participants With HbA1c <6.5% at Week 30 [Time Frame: Week 30] [Designated as safety issue: No]

  Participant whole blood samples were collected at Week 30 to determine the number of participants achieving HbA1c <6.5% at Week 30. Hemoglobin A1c is a measure of the percentage of glycated hemoglobin in the blood and provides an indication of participant blood glucose control in the 2 to 3 months prior to the evaluation.

- LS Mean Change From Baseline in Participant Body Weight at Week 30 [Time Frame: Baseline and Week 30] [Designated as safety issue: Yes]

  Participants were only permitted to wear a drape gown and undergarments (no street clothes, no shoes or socks) for this evaluation. Body weight was measured after voiding (to the nearest 0.1 kg) and measurements were collected until 2 consecutive measurements did not differ by more than 0.2 kg from each other. Body weight measurements were evaluated using a standardized, calibrated digital scale and was reported in kilograms (kg) at baseline and Week 30.

Enrollment: 480

Study Start Date:	August 2010
Study Completion Date:	October 2012
Primary Completion Date:	October 2012 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: Sitagliptin Sitagliptin phosphate 100 mg or 50 mg once daily (QD)	Drug: sitagliptin phosphate Sitagliptin tablets, orally, at a dose of 100 mg or 50 mg QD for 30 weeks. The dose level to be administered will depend on the participant's estimated glomerular filtration rate (eGFR), calculated at Visit 3 and may be adjusted as medically indicated during the study. Other Name: Januvia Drug: Placebo to Glimepiride Matching placebo tablets to glimepiride to allow for blinding.
Active Comparator: Glimepiride Glimepiride 1-6 mg QD	Drug: Glimepiride Glimepiride tablets, orally, starting at a dose of 1 mg QD, which may be gradually increased, as needed, to maximum dose of 6 mg QD for 30 weeks. The dose may also be decreased as medically indicated during the study. Other Name: Amaryl Drug: Placebo to Sitagliptin Matching placebo tablets to sitagliptin to allow for blinding.

Detailed Description:

The dose of sitagliptin will be 100 mg once daily (QD) or 50 mg QD based on the participant's estimated glomerular filtration rate (eGFR). The starting dose of glimepiride (1 mg QD) may be up-titrated as needed to optimize glycemic control over the first 18 weeks to a maximum dose of 6 mg/day, after which the dose will not be increased for the rest of the study (down-titration to avoid or control hypoglycemia is allowed).

Eligibility

Ages Eligible for Study:	65 Years to 85 Years
Genders Eligible for Study:	Both
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria

- Diagnosis of type 2 diabetes mellitus

Exclusion Criteria

- History of type 1 diabetes mellitus
- Has undergone a surgical procedure within the prior 4 weeks.
- Current participation in, or has participated, in another study with an investigational device or compound, with the prior 12 weeks, and/or is not willing to refrain from participating in any other study while participating in this study
- Hypersensitivity or contraindication to any sulfonylurea (e.g., glimepiride) medication
- Has been on an investigational or approved dipeptidyl peptidase-4 (DPP-4) inhibitor agent (e.g., sitagliptin, saxagliptin)
- Presence of human immunodeficiency virus (HIV)
- Current participation in a weight loss program or is receiving weight loss medication
- History of blood disorder, certain cancers, heart, liver or kidney disease
- Current or past use of recreational or illicit drugs, or a history of drug abuse or dependence, or increased alcohol consumption

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:

Hartley P, Shentu Y, Betz-Schiff P, Golm GT, Sisk CM, Engel SS, Shankar RR. Efficacy and Tolerability of Sitagliptin Compared with Glimepiride in Elderly Patients with Type 2 Diabetes Mellitus and Inadequate Glycemic Control: A Randomized, Double-Blind, Non-Inferiority Trial. Drugs Aging. 2015 Jun;32(6):469-76. doi: 10.1007/s40266-015-0271-z.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT01189890 History of Changes
Other Study ID Numbers:	0431-251
Study First Received:	August 25, 2010
Results First Received:	May 8, 2013
Last Updated:	June 30, 2015
Health Authority:	United States: Food and Drug Administration

Keywords provided by Merck Sharp & Dohme Corp.:
Type 2 Diabetes Mellitus, Hemoglobin A1C, glucagon-like peptide 1 (GLP-1), gastric inhibitory polypeptide (GIP), dipeptidyl peptidase 4 inhibitor (DPP-4)

Additional relevant MeSH terms:

Diabetes Mellitus	Hormones
Diabetes Mellitus, Type 2	Hormones, Hormone Substitutes, and Hormone Antagonists
Endocrine System Diseases	Hypoglycemic Agents
Glucose Metabolism Disorders	Immunologic Factors
Metabolic Diseases	Immunosuppressive Agents
Glimepiride	Incretins
Sitagliptin	Molecular Mechanisms of Pharmacological Action
Anti-Arrhythmia Agents	Pharmacologic Actions
Cardiovascular Agents	Physiological Effects of Drugs
Dipeptidyl-Peptidase IV Inhibitors	Protease Inhibitors
Enzyme Inhibitors	Therapeutic Uses

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Results First Received: May 8, 2013

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:	Type 2 Diabetes Mellitus
Interventions:	Drug: sitagliptin phosphate Drug: Glimepiride Drug: Placebo to Sitagliptin Drug: Placebo to Glimepiride

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 phosphate 100 mg once daily (QD) or 50 mg QD
Glimepiride	Glimepiride 1-6 mg QD

Participant Flow: Overall Study

	Sitagliptin	Glimepiride
STARTED	**241**	**239** [1]
COMPLETED	**204**	**200**
NOT COMPLETED	**37**	**39**
Adverse Event	**3**	**4**
Lack of Efficacy	**7**	**2**
Lost to Follow-up	**1**	**7**
Protocol Violation	**1**	**5**
Withdrawal by Subject	**15**	**11**
Non Compliance	**0**	**1**
Physician Decision	**5**	**4**
Hyperglycemia Discontinuation Criteria	**5**	**5**

[1] 3 randomized glimepiride participants did not receive study drug.

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	Sitagliptin phosphate 100 mg once daily (QD) or 50 mg QD
Glimepiride	Glimepiride 1-6 mg QD
Total	Total of all reporting groups

Baseline Measures

	Sitagliptin	Glimepiride	Total
Number of Participants [units: participants]	**241**	**239**	**480**

Age **[units: years]** **Mean (Standard Deviation)**	**70.7 (4.8)**	**70.8 (4.9)**	**70.7 (4.8)**
Gender **[units: participants]**			
Female	**130**	**148**	**278**
Male	**111**	**91**	**202**
Hemoglobin A1c (HbA1c) [1] **[units: Percentage of HbA1c]** **Mean (Standard Deviation)**	**7.78 (0.70)**	**7.78 (0.67)**	**7.78 (0.69)**
Fasting Plasma Glucose (FPG) [2] **[units: mg/dL]** **Mean (Standard Deviation)**	**168.4 (31.2)**	**169.7 (35.5)**	**169.0 (33.3)**
Body Weight [3] **[units: kg]** **Mean (Standard Deviation)**	**76.9 (15.1)**	**75.4 (16.4)**	**76.0 (15.6)**

[1] The population included all randomized participants who had a baseline HbA1c, did not take prohibited concomitant medications, had compliance >85%, and did not receive any incorrect study medication. Sitagliptin (n=197) and glimepiride (n=191).

[2] The population included all randomized participants who had a baseline FPG, did not take prohibited concomitant medications, had compliance >85%, and did not receive any incorrect study medication. Sitagliptin (n=194) and glimepiride (n=191).

[3] All randomized participants who received at least one dose of study treatment and had a body weight measurement at baseline. Sitagliptin (n=205) and glimepiride (n=203).

Outcome Measures

Hide All Outcome Measures

1. Primary: Least Squares (LS) Mean Change From Baseline in Hemoglobin A1c (HbA1c) at Week 30 [Time Frame: Baseline and Week 30]

Measure Type	Primary
Measure Title	Least Squares (LS) Mean Change From Baseline in Hemoglobin A1c (HbA1c) at Week 30
Measure Description	Participant whole blood samples were collected at baseline and Week 30 to determine the LS mean HbA1c change from baseline. HbA1c is a measure of the percentage of glycated hemoglobin in the blood and provides an indication of participant blood glucose control in the 2 to 3 months prior to the evaluation.
Time Frame	Baseline and Week 30
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 population included all randomized participants who had a baseline HbA1c, had a HbA1c at Week 30, did not take prohibited concomitant medications, had compliance >85%, and did not receive any incorrect study medication.

Reporting Groups

	Description
Sitagliptin	Sitagliptin phosphate 100 mg once daily (QD) or 50 mg QD

Glimepiride	Glimepiride 1-6 mg QD

Measured Values

	Sitagliptin	Glimepiride
Number of Participants Analyzed [units: participants]	**197**	**191**
Least Squares (LS) Mean Change From Baseline in Hemoglobin A1c (HbA1c) at Week 30 [units: Percentage of HbA1c] Least Squares Mean (95% Confidence Interval)	**-0.32 (-0.51 to -0.14)**	**-0.51 (-0.69 to -0.33)**

Statistical Analysis 1 for Least Squares (LS) Mean Change From Baseline in Hemoglobin A1c (HbA1c) at Week 30

Groups [1]	All groups
Non-Inferiority/Equivalence Test [2]	Yes
Method [3]	ANCOVA
Difference in LS Means [4]	0.19
95% Confidence Interval	0.03 to 0.34

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Details of power calculation, definition of non-inferiority margin, and other key parameters:
	The predefined non-inferiority margin was 0.4%.
[3]	Other relevant method information, such as adjustments or degrees of freedom:
	Controlled for treatment, estimated glomerular filtration rate (eGFR) stratum, age stratum, and baseline HbA1C.
[4]	Other relevant estimation information:
	No text entered.

2. Primary: Number of Participants With an Adverse Event of Symptomatic Hypoglycemia Up to Week 30 [Time Frame: Up to Week 30]

Measure Type	Primary
Measure Title	Number of Participants With an Adverse Event of Symptomatic Hypoglycemia Up to Week 30
Measure Description	Symptomatic hypoglycemia was defined as an episode with clinical symptoms attributed to hypoglycemia, without regard to glucose level. Participants were instructed to complete the Hypoglycemia Assessment Log (HAL) for any symptomatic episodes he or she believed represent hypoglycemia. If a fingerstick glucose was obtained before or shortly (i.e., within a few minutes) after treating, the value was recorded in the HAL. In addition, participants were instructed to record in the HAL any fingerstick glucose values ≤70 mg/dL (≤3.9 mmol/L) regardless of the presence of clinical symptoms.
Time Frame	Up to Week 30
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 one dose of study treatment.

Reporting Groups

	Description
Sitagliptin	Sitagliptin phosphate 100 mg once daily (QD) or 50 mg QD
Glimepiride	Glimepiride 1-6 mg QD

Measured Values

	Sitagliptin	Glimepiride
Number of Participants Analyzed [units: participants]	**241**	**236**
Number of Participants With an Adverse Event of Symptomatic Hypoglycemia Up to Week 30 [units: Participants]	**2**	**11**

Statistical Analysis 1 for Number of Participants With an Adverse Event of Symptomatic Hypoglycemia Up to Week 30

Groups [1]	All groups
Method [2]	Miettinen & Nurminen
P Value [3]	0.009
Difference in Percent Incidence [4]	-3.9
95% Confidence Interval	-7.5 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:
	Stratified by estimated glomerular filtration rate (eGFR) stratum and age stratum.
[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.

3. Primary: Number of Participants Experiencing An Adverse Event (AE) [Time Frame: Up to Week 30]

Measure Type	Primary
Measure Title	Number of Participants Experiencing An Adverse Event (AE)
Measure Description	An AE was defined as any unfavorable and unintended change in the structure, function, or chemistry of the body temporally associated with the use of the

	study treatment, whether or not considered related to the use of the treatment administered.
Time Frame	Up to Week 30
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 one dose of study treatment.

Reporting Groups

	Description
Sitagliptin	Sitagliptin phosphate 100 mg once daily (QD) or 50 mg QD
Glimepiride	Glimepiride 1-6 mg QD

Measured Values

	Sitagliptin	**Glimepiride**
Number of Participants Analyzed [units: participants]	**241**	**236**
Number of Participants Experiencing An Adverse Event (AE) [units: Participants]	**118**	**115**

No statistical analysis provided for Number of Participants Experiencing An Adverse Event (AE)

4. Primary: Number of Participants Discontinuing Study Treatment Due to An AE [Time Frame: Up to Week 30]

Measure Type	Primary
Measure Title	Number of Participants Discontinuing Study Treatment Due to An AE
Measure Description	An AE was defined as any unfavorable and unintended change in the structure, function, or chemistry of the body temporally associated with the use of the study treatment, whether or not considered related to the use of the treatment administered.
Time Frame	Up to Week 30
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 one dose of study treatment.

Reporting Groups

	Description
Sitagliptin	Sitagliptin phosphate 100 mg once daily (QD) or 50 mg

	QD
Glimepiride	Glimepiride 1-6 mg QD

Measured Values

	Sitagliptin	Glimepiride
Number of Participants Analyzed [units: participants]	**241**	**236**
Number of Participants Discontinuing Study Treatment Due to An AE [units: Participants]	**3**	**4**

No statistical analysis provided for Number of Participants Discontinuing Study Treatment Due to An AE

5. Secondary: LS Mean Change From Baseline in Fasting Plasma Glucose (FPG) at Week 30 [Time Frame: Baseline and Week 30]

Measure Type	Secondary
Measure Title	LS Mean Change From Baseline in Fasting Plasma Glucose (FPG) at Week 30
Measure Description	Plasma samples were collected from participants after an overnight fast at baseline and Week 30 to determine the mean change from baseline in participant FPG.
Time Frame	Baseline and Week 30
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 population included all randomized participants who had a FPG value at baseline and Week 30, did not take prohibited concomitant medications, had compliance >85%, and did not receive any incorrect study medication.

Reporting Groups

	Description
Sitagliptin	Sitagliptin phosphate 100 mg once daily (QD) or 50 mg QD
Glimepiride	Glimepiride 1-6 mg QD

Measured Values

	Sitagliptin	Glimepiride
Number of Participants Analyzed [units: participants]	**194**	**191**
LS Mean Change From Baseline in Fasting Plasma Glucose (FPG) at Week 30 [units: mg/dL] Least Squares Mean (95% Confidence Interval)	**-14.5 (-21.6 to -7.4)**	**-21.2 (-28.3 to -14.0)**

Statistical Analysis 1 for LS Mean Change From Baseline in Fasting Plasma Glucose (FPG) at Week 30

Groups [1]	All groups
Method [2]	ANCOVA
Difference in LS Means [3]	6.7
95% Confidence Interval	0.7 to 12.7

[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:
	Controlled for treatment, eGFR stratum, age stratum, and baseline FPG.
[3]	Other relevant estimation information:
	No text entered.

6. Secondary: Percentage of Participants With HbA1c <7.0% at Week 30 [Time Frame: Week 30]

Measure Type	Secondary
Measure Title	Percentage of Participants With HbA1c <7.0% at Week 30
Measure Description	Participant whole blood samples were collected at Week 30 to determine the number of participants achieving HbA1c <7.0% at Week 30. HbA1c is a measure of the percentage of glycated hemoglobin in the blood and provides an indication of participant blood glucose control in the 2 to 3 months prior to the evaluation.
Time Frame	Week 30
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 population included all randomized participants who had HbA1c at baseline and Week 30, did not take prohibited concomitant medications, had compliance >85%, and did not receive any incorrect study medication.

Reporting Groups

	Description
Sitagliptin	Sitagliptin phosphate 100 mg once daily (QD) or 50 mg QD
Glimepiride	Glimepiride 1-6 mg QD

Measured Values

	Sitagliptin	**Glimepiride**
Number of Participants Analyzed [units: participants]	**197**	**191**
Percentage of Participants With HbA1c <7.0% at Week 30 [units: Percentage of Participants]	**33.5**	**46.6**

Statistical Analysis 1 for Percentage of Participants With HbA1c <7.0% at Week 30

Groups [1]	All groups
Method [2]	Miettinen & Nurminen
Relative Risk [3]	0.7
95% Confidence Interval	0.6 to 0.9

[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:
	Stratified by eGFR stratum and age stratum.
[3]	Other relevant estimation information:
	No text entered.

7. Secondary: Percentage of Participants With HbA1c <6.5% at Week 30 [Time Frame: Week 30]

Measure Type	Secondary
Measure Title	Percentage of Participants With HbA1c <6.5% at Week 30
Measure Description	Participant whole blood samples were collected at Week 30 to determine the number of participants achieving HbA1c <6.5% at Week 30. Hemoglobin A1c is a measure of the percentage of glycated hemoglobin in the blood and provides an indication of participant blood glucose control in the 2 to 3 months prior to the evaluation.
Time Frame	Week 30
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 population included all randomized participants who had HbA1c at baseline and Week 30, did not take prohibited concomitant medications, had compliance >85%, and did not receive any incorrect study medication.

Reporting Groups

	Description
Sitagliptin	Sitagliptin phosphate 100 mg once daily (QD) or 50 mg QD
Glimepiride	Glimepiride 1-6 mg QD

Measured Values

	Sitagliptin	**Glimepiride**
Number of Participants Analyzed [units: participants]	**197**	**191**
Percentage of Participants With HbA1c <6.5% at Week 30	**9.1**	**20.9**

[units: Percentage of Participants]		

Statistical Analysis 1 for Percentage of Participants With HbA1c <6.5% at Week 30

Groups [1]	All groups
Method [2]	Miettinen & Nurminen
Relative Risk [3]	0.4
95% Confidence Interval	0.3 to 0.7

[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:
	Stratified by eGFR stratum and age stratum.
[3]	Other relevant estimation information:
	No text entered.

8. Secondary: LS Mean Change From Baseline in Participant Body Weight at Week 30 [Time Frame: Baseline and Week 30]

Measure Type	Secondary
Measure Title	LS Mean Change From Baseline in Participant Body Weight at Week 30
Measure Description	Participants were only permitted to wear a drape gown and undergarments (no street clothes, no shoes or socks) for this evaluation. Body weight was measured after voiding (to the nearest 0.1 kg) and measurements were collected until 2 consecutive measurements did not differ by more than 0.2 kg from each other. Body weight measurements were evaluated using a standardized, calibrated digital scale and was reported in kilograms (kg) at baseline and Week 30.
Time Frame	Baseline and Week 30
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 one dose of study treatment and had body weight measurements at baseline and at Week 30.

Reporting Groups

	Description
Sitagliptin	Sitagliptin phosphate 100 mg once daily (QD) or 50 mg QD
Glimepiride	Glimepiride 1-6 mg QD

Measured Values

	Sitagliptin	**Glimepiride**
Number of Participants Analyzed [units: participants]	**205**	**203**

LS Mean Change From Baseline in Participant Body Weight at Week 30 **[units: kg]** **Least Squares Mean (95% Confidence Interval)**	**0.4 (-0.2 to 1.0)**	**1.1 (0.5 to 1.7)**

Statistical Analysis 1 for LS Mean Change From Baseline in Participant Body Weight at Week 30

Groups [1]	All groups
Method [2]	ANCOVA
P Value [3]	0.011
Difference in LS Means [4]	-0.7
95% Confidence Interval	-1.3 to -0.2

[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:
	Controlled for treatment, eGFR stratum, age stratum, and baseline body weight.
[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.

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	Up to Week 32.
Additional Description	The safety population consisted of all randomized participants who received at least one dose of study treatment.

Reporting Groups

	Description
Sitagliptin	Sitagliptin phosphate 100 mg once daily (QD) or 50 mg QD
Glimepiride	Glimepiride 1-6 mg QD

Serious Adverse Events

	Sitagliptin	**Glimepiride**
Total, serious adverse events		
# participants affected / at risk	**7/241 (2.90%)**	**6/236 (2.54%)**

Blood and lymphatic system disorders		
Anaemia † 1		
# participants affected / at risk	**0/241 (0.00%)**	**1/236 (0.42%)**
# events	**0**	**1**
Cardiac disorders		
Angina Unstable † 1		
# participants affected / at risk	**0/241 (0.00%)**	**1/236 (0.42%)**
# events	**0**	**1**
Atrial Fibrillation † 1		
# participants affected / at risk	**1/241 (0.41%)**	**0/236 (0.00%)**
# events	**1**	**0**
Cardiac Failure Chronic † 1		
# participants affected / at risk	**0/241 (0.00%)**	**1/236 (0.42%)**
# events	**0**	**1**
Gastrointestinal disorders		
Gastrointestinal Haemorrhage † 1		
# participants affected / at risk	**0/241 (0.00%)**	**1/236 (0.42%)**
# events	**0**	**1**
Inguinal Hernia † 1		
# participants affected / at risk	**1/241 (0.41%)**	**0/236 (0.00%)**
# events	**1**	**0**
Lower Gastrointestinal Haemorrhage † 1		
# participants affected / at risk	**1/241 (0.41%)**	**0/236 (0.00%)**
# events	**1**	**0**
Infections and infestations		
Gastroenteritis † 1		
# participants affected / at risk	**1/241 (0.41%)**	**0/236 (0.00%)**
# events	**1**	**0**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Colon Cancer † 1		
# participants affected / at risk	**1/241 (0.41%)**	**0/236 (0.00%)**
# events	**1**	**0**
Malignant Melanoma † 1		
# participants affected / at risk	**1/241 (0.41%)**	**0/236 (0.00%)**
# events	**1**	**0**
Prostate Cancer † 1		
# participants affected / at risk	**1/241 (0.41%)**	**0/236 (0.00%)**
# events	**1**	**0**
Nervous system disorders		
Nerve Compression † 1		
# participants affected / at risk	**0/241 (0.00%)**	**1/236 (0.42%)**
# events	**0**	**1**
Syncope † 1		

# participants affected / at risk	0/241 (0.00%)	1/236 (0.42%)
# events	0	1
Respiratory, thoracic and mediastinal disorders		
Pulmonary Embolism † 1		
# participants affected / at risk	0/241 (0.00%)	1/236 (0.42%)
# events	0	1

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA (15.1)

Other Adverse Events

Hide Other Adverse Events

Time Frame	Up to Week 32.
Additional Description	The safety population consisted of all randomized participants who received at least one dose of study treatment.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Sitagliptin	Sitagliptin phosphate 100 mg once daily (QD) or 50 mg QD
Glimepiride	Glimepiride 1-6 mg QD

Other Adverse Events

	Sitagliptin	Glimepiride
Total, other (not including serious) adverse events		
# participants affected / at risk	34/241 (14.11%)	40/236 (16.95%)
Infections and infestations		
Nasopharyngitis † 1		
# participants affected / at risk	18/241 (7.47%)	19/236 (8.05%)
# events	20	21
Metabolism and nutrition disorders		
Hyperglycaemia † 1		
# participants affected / at risk	14/241 (5.81%)	9/236 (3.81%)
# events	17	15
Hypoglycaemia † 1		
# participants affected / at risk	3/241 (1.24%)	15/236 (6.36%)
# events	3	45

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA (15.1)

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:** Investigator may publish results for his/her study site after publication of results of entire multicenter trial, or after public disclosure of the results online if a multicenter manuscript is not planned. Sponsor must be able to review all proposed results communications regarding study 60 days prior to submission for publication/presentation. Information identified by the Sponsor as confidential must be deleted prior to submission.

Results Point of Contact:

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Publications of Results:

Hartley P, Shentu Y, Betz-Schiff P, Golm GT, Sisk CM, Engel SS, Shankar RR. Efficacy and Tolerability of Sitagliptin Compared with Glimepiride in Elderly Patients with Type 2 Diabetes Mellitus and Inadequate Glycemic Control: A Randomized, Double-Blind, Non-Inferiority Trial. Drugs Aging. 2015 Jun;32(6):469-76. doi: 10.1007/s40266-015-0271-z.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT01189890 History of Changes
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Study First Received:	August 25, 2010
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Health Authority:	United States: Food and Drug Administration

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