Comparison of Two Treatment Regimens (Sitagliptin Versus Liraglutide) on Participants Who Failed to Achieve Good Glucose Control on Metformin Alone (MK-0431-403)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

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

ClinicalTrials.gov Identifier:
NCT01296412

First received: February 14, 2011
Last updated: February 23, 2015
Last verified: February 2015
History of Changes

Purpose

This study is being done to compare the effectiveness and safety of two treatment paradigms (oral sitagliptin with or without glimepiride versus liraglutide with or without increased dosing) for the treatment of participants with Type 2 Diabetes that is not adequately controlled with metformin alone. The primary hypothesis postulated that the mean change from baseline in hemoglobin A1c (A1C) in participants treated with a sitagliptin-based treatment is non-inferior to that of participants treated with a liraglutide-based

treatment.

Condition	Intervention	Phase
Diabetes Mellitus, Type 2	Drug: sitagliptin Drug: liraglutide Drug: glimepiride Drug: metformin	Phase 3

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Efficacy Study
Intervention Model: Parallel Assignment
Masking: Open Label
Primary Purpose: Treatment

Official Title: A Phase III, Multicenter, Randomized, Open-label Clinical Trial Comparing the Efficacy and Safety of a Sitagliptin-Based Treatment Paradigm to a Liraglutide-Based Treatment Paradigm in Patients With Type 2 Diabetes Mellitus Who Have Inadequate Glycemic Control on Metformin Monotherapy

Resource links provided by NLM:

MedlinePlus related topics: Diabetes Type 2

Drug Information available for: Metformin Metformin hydrochloride Glimepiride Liraglutide Sitagliptin Sitagliptin phosphate

U.S. FDA Resources

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

Primary Outcome Measures:

- Change From Baseline in Hemoglobin A1c (A1C) [Time Frame: Baseline and Week 26] [Designated as safety issue: No]

  A1C is measured as percent. Thus, this change from baseline reflects the Week 26 A1C percent minus the Week 0 A1C percent.

Secondary Outcome Measures:

- Change From Baseline in Fasting Plasma Glucose (FPG) [Time Frame: Baseline and Week 26] [Designated as safety issue: No]

  Change from baseline at Week 26 is defined as Week 26 minus Week 0.

- Percentage of Participants Reaching A1C Goal of <7.0% [Time Frame: Week 26] [Designated as safety issue: No]
- Percentage of Participants Reaching A1C Goal of <6.5% [Time Frame: Week 26] [Designated as safety issue: No]

Enrollment:	653
Study Start Date:	March 2011
Study Completion Date:	February 2012
Primary Completion Date:	February 2012 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: Sitagliptin +/- glimepiride Sitagliptin 100 mg tablet orally once daily for 26 weeks. Participants continued their stable dose of metformin >=1500 mg orally daily. Participants may have received glimepiride orally for glycemic control.	Drug: sitagliptin 100 mg tablet, orally, once daily. Other Name: MK-0431, Januvia®, Tesavel®, Xelevia®, Ristaben® Drug: glimepiride starting dose of 1 mg tablet (up-titrated as needed), once daily, as needed, after Week 12. Other Name: Amaryl® Drug: metformin metformin tablets at a dose of ≥1500 mg per day Other Name: Fortamet®, Glucophage®, Glucophage® XR, Glumetza®, Riomet®, Metgluco®, Glycoran®
Active Comparator: Liraglutide Liraglutide subcutaneous injection once daily for 26 weeks (starting dose 0.6 mg daily up-titrated to 1.2 mg daily on Day 8). Participants continued their stable dose of metformin >=1500 mg orally daily. Participants may have had their liraglutide dose uptitrated to 1.8 mg daily for glycemic control.	Drug: liraglutide 0.6 mg by subcutaneous (pen) injection, once daily, on Days 1-7; up-titrated on Day 8 to 1.2 mg daily. At Week 12, dose may be increased to 1.8 mg once daily for participants who did not meet protocol-specified glycemic goals. Other Name: Victoza® Drug: metformin metformin tablets at a dose of ≥1500 mg per day Other Name: Fortamet®, Glucophage®, Glucophage® XR, Glumetza®, Riomet®, Metgluco®, Glycoran®

Eligibility

Ages Eligible for Study:	18 Years to 79 Years
Genders Eligible for Study:	Both
Accepts Healthy Volunteers:	No

Criteria

Inclusion criteria

- Type 2 diabetes mellitus.
- On stable dose of metformin monotherapy at a dose of at least 1500 mg per day for at least 12 weeks and a hemoglobin A1C ≥7.0% and ≤11.0%.
- Capable of using a liraglutide pen device.

Exclusion criteria

- History of Type 1 Diabetes mellitus.
- Use of any oral antihyperglycemic agent (AHA) besides metformin, within the prior 12 weeks of screening.
- Cardiovascular disorders within the past 3 months including acute coronary syndrome or new or worsening symptoms of coronary heart disease, coronary artery intervention, stroke, or transient ischemic neurological disorder.
- Impaired liver function.
- Impaired kidney function.
- History of malignancy or clinically important hematological disorder that requires disease-specific treatment (chemotherapy, radiation therapy, surgery) or, in the opinion of the investigator, is likely to recur during the duration of the study.
- History of leukemia, lymphoma, aplastic anemia, myeloproliferative or myelodysplastic diseases, thrombocytopenia, or malignant melanoma, regardless of the time since treatment.
- Pregnancy or breastfeeding, or intention to become pregnant or donate eggs within the projected duration of the study.
- Participation in another study with an investigational drug or device within 12 weeks prior to screening.
- History of hypersensitivity or any contraindication to sitagliptin, liraglutide, glimepiride, or metformin based upon the labels of the country of the investigational site.
- Participation in a weight loss program and not yet in maintenance phase, or starting of a weight loss medication (such as orlistat or phentermine) within the prior 8 weeks.
- Surgery within the prior 4 weeks or major surgery planned during the study.
- Personal or family history of medullary thyroid carcinoma (MTC) or multiple endocrine neoplasia syndrome type 2 (MEN 2).
- User of recreational or illicit drugs or recent history (within the last year) of drug abuse 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 automatically indexed to this study by ClinicalTrials.gov Identifier (NCT Number):

Charbonnel B, Steinberg H, Eymard E, Xu L, Thakkar P, Prabhu V, Davies MJ, Engel SS. Efficacy and safety over 26 weeks of an oral treatment strategy including sitagliptin compared with an injectable treatment strategy with liraglutide in patients with type 2 diabetes mellitus inadequately controlled on metformin: a randomised clinical trial. Diabetologia. 2013 Jul;56(7):1503-11. doi: 10.1007/s00125-013-2905-1. Epub 2013 Apr 19.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT01296412 History of Changes
Other Study ID Numbers:	0431-403
Study First Received:	February 14, 2011
Results First Received:	February 5, 2013
Last Updated:	February 23, 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	Immunologic Factors
Glimepiride	Immunosuppressive Agents

Liraglutide
Metformin
Sitagliptin
Anti-Arrhythmia Agents
Cardiovascular Agents
Dipeptidyl-Peptidase IV Inhibitors
Incretins
Molecular Mechanisms of Pharmacological Action
Pharmacologic Actions
Physiological Effects of Drugs
Protease Inhibitors
Therapeutic Uses

ClinicalTrials.gov processed this record on April 13, 2016

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Results First Received: February 5, 2013

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Efficacy Study; Intervention Model: Parallel Assignment; Masking: Open Label; Primary Purpose: Treatment
Condition:	Diabetes Mellitus, Type 2
Interventions:	Drug: sitagliptin Drug: liraglutide Drug: glimepiride 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 +/- Glimepiride	Sitagliptin 100 mg tablet once daily for 26 weeks. Participants continued their stable dose of metformin >=1500 mg orally daily. Participants may have received glimepiride for glycemic control.
Liraglutide	Liraglutide subcutaneous injection once daily for 26 weeks (starting dose 0.6 mg daily up-titrated to 1.2 mg daily on Day 8). Participants continued their stable dose of metformin >=1500 mg orally daily. Participants may have had their liraglutide dose uptitrated to 1.8 mg daily for glycemic control.

Participant Flow: Overall Study

	Sitagliptin +/- Glimepiride	Liraglutide
STARTED	**326**	**327**
COMPLETED	**275**	**257**
NOT COMPLETED	**51**	**70**
Adverse Event	**8**	**29**
Lack of Efficacy	**1**	**0**
Lost to Follow-up	**10**	**7**
Non-compliance with study drug	**1**	**2**
Other reason not specified	**20**	**15**
Physician Decision	**1**	**3**
Pregnancy	**0**	**1**
Withdrawal by Subject	**10**	**13**

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 +/- Glimepiride	Sitagliptin 100 mg tablet once daily for 26 weeks. Participants continued their stable dose of metformin >=1500 mg orally daily. Participants may have received glimepiride for glycemic control.
Liraglutide	Liraglutide subcutaneous injection once daily for 26 weeks (starting dose 0.6 mg daily up-titrated to 1.2 mg daily on Day 8). Participants continued their stable dose of metformin >=1500 mg orally daily. Participants may have had their liraglutide dose uptitrated to 1.8 mg daily for glycemic control.
Total	Total of all reporting groups

Baseline Measures

	Sitagliptin +/- Glimepiride	Liraglutide	Total
Number of Participants	**326**	**327**	**653**

[units: participants]			
Age **[units: years]** **Mean (Standard Deviation)**	**56.9 (10.0)**	**57.6 (10.8)**	**57.3 (10.4)**
Gender **[units: participants]**			
Female	**148**	**147**	**295**
Male	**178**	**180**	**358**
Hemoglobin A1c (A1C) [1] **[units: Percent]** **Mean (Standard Deviation)**	**8.2 (1.1)**	**8.1 (0.9)**	**8.2 (1.0)**
Fasting Plasma Glucose [2] **[units: mg/dL]** **Mean (Standard Deviation)**	**174.1 (43.7)**	**172.9 (40.8)**	**173.5 (42.3)**

[1] A1C baseline values are presented for participants with data: Sitagliptin + metformin, n=325; liraglutide + metformin, n= 325; total population, n=650

[2] FPG baseline values are presented for participants with data: Sitagliptin + metformin, n=325; liraglutide + metformin, n= 325; total population, n=650

Outcome Measures

Hide All Outcome Measures

1. Primary: Change From Baseline in Hemoglobin A1c (A1C) [Time Frame: Baseline and Week 26]

Measure Type	Primary
Measure Title	Change From Baseline in Hemoglobin A1c (A1C)
Measure Description	A1C is measured as percent. Thus, this change from baseline reflects the Week 26 A1C percent minus the Week 0 A1C percent.
Time Frame	Baseline and Week 26
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.
Per-protocol population defined as participants who had a measurement at baseline and a measurement after at least 24 weeks (i.e., 168 days) of treatment, and did not have any major protocol violations.

Reporting Groups

	Description
Sitagliptin +/- Glimepiride	Sitagliptin 100 mg tablet once daily for 26 weeks. Participants continued their stable dose of metformin >=1500 mg orally daily. Participants may have received glimepiride for glycemic control.
Liraglutide	Liraglutide subcutaneous injection once daily for 26 weeks (starting dose 0.6 mg daily up-titrated to 1.2 mg daily on Day 8). Participants continued their stable dose of metformin >=1500 mg orally daily. Participants may have had their liraglutide dose uptitrated to 1.8 mg daily for glycemic control.

Measured Values

	Sitagliptin +/- Glimepiride	Liraglutide
Number of Participants Analyzed [units: participants]	**269**	**253**
Change From Baseline in Hemoglobin A1c (A1C) [units: percent] Least Squares Mean (95% Confidence Interval)	**-1.32 (-1.42 to -1.23)**	**-1.42 (-1.51 to -1.32)**

Statistical Analysis 1 for Change From Baseline in Hemoglobin A1c (A1C)

Groups [1]	All groups
Non-Inferiority/Equivalence Test [2]	Yes
Method [3]	ANCOVA
Difference in least squares mean [4]	0.09
95% Confidence Interval	-0.05 to 0.23

[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 sitagliptin-based treatment paradigm was to be declared non-inferior to the liraglutide-based treatment paradigm in lowering A1C at Week 26 if the upper bound of 95% confidence intervals of between group difference was less than the non-inferiority margin of 0.4%.
[3]	Other relevant method information, such as adjustments or degrees of freedom:
	The ANCOVA model included a term for treatment paradigm and a covariate for baseline value.
[4]	Other relevant estimation information:
	No text entered.

2. Secondary: Change From Baseline in Fasting Plasma Glucose (FPG) [Time Frame: Baseline and Week 26]

Measure Type	Secondary
Measure Title	Change From Baseline in Fasting Plasma Glucose (FPG)
Measure Description	Change from baseline at Week 26 is defined as Week 26 minus Week 0.
Time Frame	Baseline and Week 26
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.
Per-protocol population defined as participants who had a measurement at baseline and a measurement after at least 24 weeks (i.e., 168 days) of treatment, and did not have any major protocol violations.

Reporting Groups

	Description
Sitagliptin +/- Glimepiride	Sitagliptin 100 mg tablet once daily for 26 weeks. Participants continued their stable dose of metformin >=1500 mg orally daily. Participants may have received glimepiride for glycemic control.
Liraglutide	Liraglutide subcutaneous injection once daily for 26 weeks (starting dose 0.6 mg daily up-titrated to 1.2 mg daily on Day 8). Participants continued their stable dose of metformin >=1500 mg orally daily. Participants may have had their liraglutide dose uptitrated to 1.8 mg daily for glycemic control.

Measured Values

	Sitagliptin +/- Glimepiride	Liraglutide
Number of Participants Analyzed [units: participants]	**269**	**252**
Change From Baseline in Fasting Plasma Glucose (FPG) [units: mg/dL] Least Squares Mean (95% Confidence Interval)	**-33.7 (-37.5 to -29.9)**	**-39.6 (-43.6 to -35.7)**

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

Groups [1]	All groups
Method [2]	ANCOVA
Difference in least squares mean [3]	5.9
95% Confidence Interval	0.5 to 11.4

[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:
	The ANCOVA model included a term for treatment paradigm and a covariate for baseline value.
[3]	Other relevant estimation information:
	No text entered.

3. Secondary: Percentage of Participants Reaching A1C Goal of <7.0% [Time Frame: Week 26]

Measure Type	Secondary
Measure Title	Percentage of Participants Reaching A1C Goal of <7.0%
Measure Description	No text entered.
Time Frame	Week 26
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.

Per-protocol population defined as participants who had a measurement at baseline and a measurement after at least 24 weeks (i.e., 168 days) of treatment, and did not have any major protocol violations.

Reporting Groups

	Description
Sitagliptin +/- Glimepiride	Sitagliptin 100 mg tablet once daily for 26 weeks. Participants continued their stable dose of metformin >=1500 mg orally daily. Participants may have received glimepiride for glycemic control.
Liraglutide	Liraglutide subcutaneous injection once daily for 26 weeks (starting dose 0.6 mg daily up-titrated to 1.2 mg daily on Day 8). Participants continued their stable dose of metformin >=1500 mg orally daily. Participants may have had their liraglutide dose uptitrated to 1.8 mg daily for glycemic control.

Measured Values

	Sitagliptin +/- Glimepiride	Liraglutide
Number of Participants Analyzed [units: participants]	**269**	**253**
Percentage of Participants Reaching A1C Goal of <7.0% [units: percentage of participants]	**62.8**	**72.3**

Statistical Analysis 1 for Percentage of Participants Reaching A1C Goal of <7.0%

Groups [1]	All groups
Method [2]	Miettinen & Nurminen
Difference in percent [3]	-9.5
95% Confidence Interval	-17.4 to -1.5

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Other relevant estimation information:
	No text entered.

4. Secondary: Percentage of Participants Reaching A1C Goal of <6.5% [Time Frame: Week 26]

Measure Type	Secondary
Measure Title	Percentage of Participants Reaching A1C Goal of <6.5%
Measure Description	No text entered.
Time Frame	Week 26
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.
Per-protocol population defined as participants who had a measurement at baseline and a measurement after at least 24 weeks (i.e., 168 days) of treatment, and did not have any major protocol violations.

Reporting Groups

	Description
Sitagliptin +/- Glimepiride	Sitagliptin 100 mg tablet once daily for 26 weeks. Participants continued their stable dose of metformin >=1500 mg orally daily. Participants may have received glimepiride for glycemic control.
Liraglutide	Liraglutide subcutaneous injection once daily for 26 weeks (starting dose 0.6 mg daily up-titrated to 1.2 mg daily on Day 8). Participants continued their stable dose of metformin >=1500 mg orally daily. Participants may have had their liraglutide dose uptitrated to 1.8 mg daily for glycemic control.

Measured Values

	Sitagliptin +/- Glimepiride	**Liraglutide**
Number of Participants Analyzed [units: participants]	**269**	**253**
Percentage of Participants Reaching A1C Goal of <6.5% [units: percentage of participants]	**33.8**	**38.3**

Statistical Analysis 1 for Percentage of Participants Reaching A1C Goal of <6.5%

Groups [1]	All groups
Method [2]	Miettinen & Nurminen
Difference in percent [3]	-4.5
95% Confidence Interval	-12.7 to 3.7

[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:
	No text entered.
[3]	Other relevant estimation information:
	No text entered.

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	No text entered.
Additional Description	Safety analyses were performed on the all participants as treated population (defined as participants who received at least 1 dose of study therapy). Participants were included in the reporting group corresponding to the actual study treatment received. Three participants randomized to therapy did not receive any study therapy.

Reporting Groups

	Description
Sitagliptin +/- Glimepiride	Sitagliptin 100 mg tablet once daily for 26 weeks. Participants continued their stable dose of metformin >=1500 mg orally daily. Participants may have received glimepiride for glycemic control.
Liraglutide	Liraglutide subcutaneous injection once daily for 26 weeks (starting dose 0.6 mg daily up-titrated to 1.2 mg daily on Day 8). Participants continued their stable dose of metformin >=1500 mg orally daily. Participants may have had their liraglutide dose uptitrated to 1.8 mg daily for glycemic control.

Serious Adverse Events

	Sitagliptin +/- Glimepiride	Liraglutide
Total, serious adverse events		
# participants affected / at risk	**17/326 (5.21%)**	**12/324 (3.70%)**
Cardiac disorders		
Atrial fibrillation [1]		
# participants affected / at risk	**1/326 (0.31%)**	**0/324 (0.00%)**
# events	**1**	**0**
Coronary artery disease [1]		
# participants affected / at risk	**1/326 (0.31%)**	**0/324 (0.00%)**
# events	**1**	**0**
Myocardial infarction [1]		
# participants affected / at risk	**1/326 (0.31%)**	**0/324 (0.00%)**
# events	**1**	**0**
Gastrointestinal disorders		
Inguinal hernia [1]		
# participants affected / at risk	**1/326 (0.31%)**	**0/324 (0.00%)**
# events	**1**	**0**
General disorders		
Accidental death [1]		
# participants affected / at risk	**1/326 (0.31%)**	**0/324 (0.00%)**
# events	**1**	**0**
Non-cardiac chest pain [1]		
# participants affected / at risk	**1/326 (0.31%)**	**1/324 (0.31%)**
# events	**1**	**1**
Infections and infestations		
Cellulitis [1]		
# participants affected / at risk	**1/326 (0.31%)**	**0/324 (0.00%)**
# events	**1**	**0**
Cholecystitis infective [1]		
# participants affected / at risk	**1/326 (0.31%)**	**0/324 (0.00%)**
# events	**1**	**0**
Injury, poisoning and procedural complications		
Craniocerebral injury [1]		

# participants affected / at risk	1/326 (0.31%)	0/324 (0.00%)
# events	1	0
Rib fracture [1]		
# participants affected / at risk	1/326 (0.31%)	0/324 (0.00%)
# events	1	0
Road traffic accident [1]		
# participants affected / at risk	2/326 (0.61%)	0/324 (0.00%)
# events	2	0
Spinal compression fracture [1]		
# participants affected / at risk	1/326 (0.31%)	0/324 (0.00%)
# events	1	0
Sternal fracture [1]		
# participants affected / at risk	1/326 (0.31%)	0/324 (0.00%)
# events	1	0
Subcutaneous hematoma [1]		
# participants affected / at risk	1/326 (0.31%)	0/324 (0.00%)
# events	1	0
Investigations		
Prostatic specific antigen increased [1]		
# participants affected / at risk	0/326 (0.00%)	1/324 (0.31%)
# events	0	1
Metabolism and nutrition disorders		
Hypoglycaemia [1]		
# participants affected / at risk	1/326 (0.31%)	0/324 (0.00%)
# events	1	0
Musculoskeletal and connective tissue disorders		
Muscle haemorrhage [1]		
# participants affected / at risk	1/326 (0.31%)	0/324 (0.00%)
# events	1	0
Osteoarthritis [1]		
# participants affected / at risk	0/326 (0.00%)	1/324 (0.31%)
# events	0	1
Spinal column stenosis [1]		
# participants affected / at risk	0/326 (0.00%)	1/324 (0.31%)
# events	0	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Breast cancer [1]		
# participants affected / at risk	0/326 (0.00%)	1/324 (0.31%)
# events	0	1
Malignant melanoma stage I [1]		
# participants affected / at risk	1/326 (0.31%)	0/324 (0.00%)
# events	1	0
Prostate cancer [1]		
# participants affected / at risk	0/326 (0.00%)	1/324 (0.31%)

# events	0	1
Squamous cell carcinoma [1]		
# participants affected / at risk	1/326 (0.31%)	0/324 (0.00%)
# events	1	0
Nervous system disorders		
Encephalopathy [1]		
# participants affected / at risk	0/326 (0.00%)	1/324 (0.31%)
# events	0	1
Sciatica [1]		
# participants affected / at risk	0/326 (0.00%)	1/324 (0.31%)
# events	0	2
Transient ischaemic attack [1]		
# participants affected / at risk	0/326 (0.00%)	1/324 (0.31%)
# events	0	1
Renal and urinary disorders		
Ureteric stenosis [1]		
# participants affected / at risk	1/326 (0.31%)	0/324 (0.00%)
# events	1	0
Urinary tract obstruction [1]		
# participants affected / at risk	1/326 (0.31%)	0/324 (0.00%)
# events	1	0
Respiratory, thoracic and mediastinal disorders		
Bronchitis chronic [1]		
# participants affected / at risk	1/326 (0.31%)	0/324 (0.00%)
# events	1	0
Chronic obstructive pulmonary disease [1]		
# participants affected / at risk	1/326 (0.31%)	1/324 (0.31%)
# events	1	1
Emphysema [1]		
# participants affected / at risk	1/326 (0.31%)	0/324 (0.00%)
# events	1	0
Skin and subcutaneous tissue disorders		
Angioedema [1]		
# participants affected / at risk	0/326 (0.00%)	1/324 (0.31%)
# events	0	1
Dermatitis allergic [1]		
# participants affected / at risk	0/326 (0.00%)	1/324 (0.31%)
# events	0	1
Vascular disorders		
Blue toe syndrome [1]		
# participants affected / at risk	1/326 (0.31%)	0/324 (0.00%)
# events	1	0
Peripheral ischaemia [1]		
# participants affected / at risk	1/326 (0.31%)	0/324 (0.00%)

# events	**1**	**0**

1 Term from vocabulary, MedDRA (14.1)

Other Adverse Events

Hide Other Adverse Events

Time Frame	No text entered.
Additional Description	Safety analyses were performed on the all participants as treated population (defined as participants who received at least 1 dose of study therapy). Participants were included in the reporting group corresponding to the actual study treatment received. Three participants randomized to therapy did not receive any study therapy.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Sitagliptin +/- Glimepiride	Sitagliptin 100 mg tablet once daily for 26 weeks. Participants continued their stable dose of metformin >=1500 mg orally daily. Participants may have received glimepiride for glycemic control.
Liraglutide	Liraglutide subcutaneous injection once daily for 26 weeks (starting dose 0.6 mg daily up-titrated to 1.2 mg daily on Day 8). Participants continued their stable dose of metformin >=1500 mg orally daily. Participants may have had their liraglutide dose uptitrated to 1.8 mg daily for glycemic control.

Other Adverse Events

	Sitagliptin +/- Glimepiride	**Liraglutide**
Total, other (not including serious) adverse events		
# participants affected / at risk	**58/326 (17.79%)**	**97/324 (29.94%)**
Gastrointestinal disorders		
Diarrhoea [1]		
# participants affected / at risk	**7/326 (2.15%)**	**35/324 (10.80%)**
# events	**9**	**42**
Nausea [1]		
# participants affected / at risk	**10/326 (3.07%)**	**63/324 (19.44%)**
# events	**13**	**73**
Vomiting [1]		
# participants affected / at risk	**6/326 (1.84%)**	**21/324 (6.48%)**
# events	**10**	**25**
Metabolism and nutrition disorders		
Decreased appetite [1]		
# participants affected / at risk	**4/326 (1.23%)**	**21/324 (6.48%)**
# events	**4**	**21**
Hypoglycaemia [1]		

# participants affected / at risk	41/326 (12.58%)	15/324 (4.63%)
# events	89	31

1 Term from vocabulary, MedDRA (14.1)

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

Charbonnel B, Steinberg H, Eymard E, Xu L, Thakkar P, Prabhu V, Davies MJ, Engel SS. Efficacy and safety over 26 weeks of an oral treatment strategy including sitagliptin compared with an injectable treatment strategy with liraglutide in patients with type 2 diabetes mellitus inadequately controlled on metformin: a randomised clinical trial. Diabetologia. 2013 Jul;56(7):1503-11. doi: 10.1007/s00125-013-2905-1. Epub 2013 Apr 19.

Responsible Party: Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier: NCT01296412 History of Changes
Other Study ID Numbers: 0431-403
Study First Received: February 14, 2011
Results First Received: February 5, 2013
Last Updated: February 23, 2015

Health Authority: United States: Food and Drug Administration

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

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