Sitagliptin Mechanism of Action Study in Patients With Type 2 Diabetes Mellitus (0431-059)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

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

ClinicalTrials.gov Identifier:
NCT00704132

First received: June 23, 2008
Last updated: August 13, 2015
Last verified: August 2015
History of Changes

Purpose

A clinical study to determine the safety, efficacy and the way sitagliptin works in patients with Type 2 Diabetes Mellitus who have inadequate glycemic (blood sugar) control.

Condition	Intervention	Phase
Type 2 Diabetes Mellitus (T2DM)	Drug: Comparator: sitagliptin phosphate Drug: Comparator: placebo (unspecified)	Phase 1

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

Official Title: A Randomized, Placebo-Controlled Study to Evaluate the Safety, Efficacy and Mechanism of Action of MK0431/Sitagliptin in Patients With Type 2 Diabetes Mellitus Who Have Inadequate Glycemic Control

Resource links provided by NLM:

MedlinePlus related topics: Diabetes Type 2

Drug Information available for: Sitagliptin Sitagliptin phosphate

U.S. FDA Resources

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

Primary Outcome Measures:

- Change From Baseline in Glucose 5-Hour Incremental AUC at Week 6 [Time Frame: Baseline and Week 6] [Designated as safety issue: No]

Participants underwent the 5-hour meal test prior to randomization (baseline) and was repeated at the conclusion of the 6-week double-blind study period. The change from baseline in Glucose 5-Hour Incremental AUC at Week 6 is computed as the difference between the Week 6 measurement and the baseline measurement.

Enrollment:	57
Study Start Date:	February 2007
Study Completion Date:	April 2010
Primary Completion Date:	April 2010 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: sitagliptin Participants randomized to this arm will be administered sitagliptin 100mg daily, for six weeks.	Drug: Comparator: sitagliptin phosphate Sitagliptin tablet 100 mg, administered once daily before the morning meal.
Placebo Comparator: Placebo Participants randomized to this arm will be administered matching placebo, daily for six weeks.	Drug: Comparator: placebo (unspecified) Matching placebo tablet, administered once daily before the morning meal.

Eligibility

Ages Eligible for Study:	30 Years to 70 Years
Genders Eligible for Study:	Both
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- Participant has type 2 diabetes mellitus
- Males
- Females who are highly unlikely to become pregnant
- Participants poorly controlled without taking any, or taking one or two oral antidiabetic medications

Exclusion Criteria:

- Participant has a history of type 1 diabetes mellitus or history of ketoacidosis
- Participant required insulin therapy within the prior 8 weeks
- Participant is on or has been taking TZDs such as Actos® (pioglitazone) or Avandia® (rosiglitazone) within the prior 12 weeks of the screening visit

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT00704132

Sponsors and Collaborators

Merck Sharp & Dohme Corp.

Investigators

Study Director: Medical Monitor Merck Sharp & Dohme Corp.

More Information

Additional Information:

MedWatch - FDA maintained medical product safety Information

Merck: Patient & Caregiver U.S. Product Web Site

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

Muscelli E, Casolaro A, Gastaldelli A, Mari A, Seghieri G, Astiarraga B, Chen Y, Alba M, Holst J, Ferrannini E. Mechanisms for the antihyperglycemic effect of sitagliptin in patients with type 2 diabetes. J Clin Endocrinol Metab. 2012 Aug;97(8):2818-26. doi: 10.1210/jc.2012-1205. Epub 2012 Jun 8.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00704132 History of Changes
Other Study ID Numbers:	0431-059 2006_511
Study First Received:	June 23, 2008
Results First Received:	April 21, 2011
Last Updated:	August 13, 2015
Health Authority:	Italy: Ministry of Health

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	Incretins
Metabolic Diseases	Molecular Mechanisms of Pharmacological Action
Sitagliptin	Pharmacologic Actions
Dipeptidyl-Peptidase IV Inhibitors	Physiological Effects of Drugs
Enzyme Inhibitors	Protease Inhibitors

ClinicalTrials.gov processed this record on April 13, 2016

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Results First Received: April 21, 2011

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Caregiver, Investigator); Primary Purpose: Treatment
Condition:	Type 2 Diabetes Mellitus (T2DM)
Interventions:	Drug: Comparator: sitagliptin phosphate Drug: Comparator: placebo (unspecified)

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
57 participants were enrolled in this study. Of these, 7 participants with normal fasting glucose (NFG) only underwent pre-randomization experiments and did not receive an allocation number, were not randomized to one of the treatment groups, and did not receive double-blind study medication.

Reporting Groups

	Description
Sitagliptin	Participants were administered sitagliptin 100 mg tablet once daily before the morning meal for six weeks.
Placebo	Participants were administered sitagliptin matching placebo tablet once daily before the morning meal for six weeks.

Participant Flow: Overall Study

	Sitagliptin	Placebo
STARTED	**26**	**24**
COMPLETED	**25**	**22**
NOT COMPLETED	**1**	**2**
Clinical Adverse Experience	**1**	**0**
Lack of Efficacy	**0**	**1**
Withdrawal by Subject	**0**	**1**

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	Participants were administered sitagliptin 100 mg tablet once daily before the morning meal for six weeks.
Placebo	Participants were administered sitagliptin matching placebo tablet once daily before the morning meal for six weeks.
Total	Total of all reporting groups

Baseline Measures

	Sitagliptin	Placebo	Total
Number of Participants [units: participants]	**26**	**24**	**50**
Age, Customized [units: participants]	**26**	**24**	**50**
Gender [units: participants]			
Female	**7**	**8**	**15**
Male	**19**	**16**	**35**

Outcome Measures

1. Primary: Change From Baseline in Glucose 5-Hour Incremental AUC at Week 6 [Time Frame: Baseline and Week 6]

Hide Outcome Measure 1

Measure Type	Primary
Measure Title	Change From Baseline in Glucose 5-Hour Incremental AUC at Week 6
Measure Description	Participants underwent the 5-hour meal test prior to randomization (baseline) and was repeated at the conclusion of the 6-week double-blind study period. The change from baseline in Glucose 5-Hour Incremental AUC at Week 6 is computed as the difference between the Week 6 measurement and the baseline measurement.
Time Frame	Baseline and Week 6
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, which includes all randomized participants who had a baseline value, received at least one dose of randomized treatment, and had a measurement at Week 6.

Reporting Groups

	Description
Sitagliptin	Participants were administered sitagliptin 100 mg tablet once daily before the morning meal for six weeks.
Placebo	Participants were administered sitagliptin matching placebo tablet once daily before the morning meal for six weeks.

Measured Values

	Sitagliptin	**Placebo**
Number of Participants Analyzed [units: participants]	**25**	**22**
Change From Baseline in Glucose 5-Hour Incremental AUC at Week 6 [units: mg*hr/dL] Least Squares Mean (95% Confidence Interval)	**-83.9 (-125.9 to -41.9)**	**27.0 (-16.0 to 70.1)**

Statistical Analysis 1 for Change From Baseline in Glucose 5-Hour Incremental AUC at Week 6

Groups [1]	All groups
Method [2]	ANCOVA
P Value [3]	<0.001
Difference in Least-Squares Mean [4]	-111.0
95% Confidence Interval	-158.0 to -63.9

[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:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	Sitagliptin minus Placebo

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	No text entered.
Additional Description	The analyses for all safety outcomes used the All Patients as Treated (APaT) approach. The APaT population used all randomized participants who received at least 1 dose of study therapy.

Reporting Groups

	Description
Sitagliptin	Participants were administered sitagliptin 100 mg tablet once daily before the morning meal for six weeks.
Placebo	Participants were administered sitagliptin matching placebo tablet once daily before the morning meal for six weeks.

Serious Adverse Events

	Sitagliptin	Placebo
Total, serious adverse events		
# participants affected / at risk	**1/26 (3.85%)**	**0/24 (0.00%)**
Ear and labyrinth disorders		
Vertigo positional † 1		
# participants affected / at risk	**1/26 (3.85%)**	**0/24 (0.00%)**
# events	**1**	**0**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA 12.2

Other Adverse Events

Hide Other Adverse Events

Time Frame	No text entered.
Additional Description	The analyses for all safety outcomes used the All Patients as Treated (APaT) approach. The APaT population used all randomized participants who received at least 1 dose of study therapy.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Sitagliptin	Participants were administered sitagliptin 100 mg tablet once daily before the morning meal for six weeks.
Placebo	Participants were administered sitagliptin matching placebo tablet once daily before the morning meal for six weeks.

Other Adverse Events

	Sitagliptin	Placebo
Total, other (not including serious) adverse events		
# participants affected / at risk	**0/26 (0.00%)**	**0/24 (0.00%)**

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. SPONSOR review can be expedited to meet publication guidelines.

Results Point of Contact:

Name/Title: Senior Vice President, Global Clinical Development

Organization: Merck Sharp & Dohme Corp.
e-mail: ClinicalTrialsDisclosure@merck.com

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Muscelli E, Casolaro A, Gastaldelli A, Mari A, Seghieri G, Astiarraga B, Chen Y, Alba M, Holst J, Ferrannini E. Mechanisms for the antihyperglycemic effect of sitagliptin in patients with type 2 diabetes. J Clin Endocrinol Metab. 2012 Aug;97(8):2818-26. doi: 10.1210/jc.2012-1205. Epub 2012 Jun 8.

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