Trial record **1 of 1** for: NCT00532935

Previous Study | Return to List | Next Study

MK0431A vs. Pioglitazone in Patients With Type 2 Diabetes Mellitus (0431A-066)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

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

ClinicalTrials.gov Identifier:
NCT00532935

First received: September 19, 2007
Last updated: December 16, 2015
Last verified: December 2015
History of Changes

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

Purpose

A study to evaluate the efficacy and safety of MK0431A in comparison to a commonly used medication in patients with type 2 diabetes

Condition	Intervention	Phase
Type 2 Diabetes Mellitus	Drug: sitagliptin phosphate (+) metformin hydrochloride Drug: Comparator: pioglitazone	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 Randomized, Active-Comparator (Pioglitazone) Controlled Clinical Trial to Study the Efficacy and Safety of the MK0431A (A Fixed-Dose Combination Tablet of Sitagliptin and Metformin) in Patients With Type 2 Diabetes Mellitus

Resource links provided by NLM:

MedlinePlus related topics: Diabetes Type 2

Drug Information available for: Metformin Metformin hydrochloride Pioglitazone Pioglitazone hydrochloride Sitagliptin Sitagliptin phosphate

U.S. FDA Resources

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

Primary Outcome Measures:

- Change From Baseline in A1C at Week 32 [Time Frame: Baseline and Week 32] [Designated as safety issue: No]

A1C is measured as a percent. Thus this change from baseline reflects the Week 32 A1C percent minus the baseline A1C percent

Secondary Outcome Measures:

- Change From Baseline in Fasting Plasma Glucose (FPG) at Week 1 [Time Frame: Baseline and Week 1] [Designated as safety issue: No]

  Change from baseline reflects the Week 1 FPG minus the baseline FPG. At Week 1, the dose was 50/500 mg b.i.d. for Sita/Met FDC and 30 mg q.d. for pioglitazone

- Change From Baseline in 2-hour Post-Meal Glucose (PMG) at Week 32 [Time Frame: Baseline and Week 32] [Designated as safety issue: No]

  Change from baseline reflects the Week 32 2-hour PMG minus the baseline 2-hour PMG

- Change From Baseline in FPG at Week 32 [Time Frame: Baseline and Week 32] [Designated as safety issue: No]

  Change from baseline reflects the Week 32 FPG minus the baseline FPG

- Percent of Participants With A1C <7.0% at Week 32 [Time Frame: Week 32] [Designated as safety issue: No]

Enrollment:	517
Study Start Date:	January 2008
Study Completion Date:	October 2009
Primary Completion Date:	October 2009 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: 1 Sitagliptin phosphate (+) metformin hydrochloride	Drug: sitagliptin phosphate (+) metformin hydrochloride sitagliptin phosphate (+) metformin hydrochloride 50/500 mg tablet bid, titrating up to sitagliptin phosphate (+) metformin hydrochloride 50/1000 mg tablet for an ~32 wk treatment period Other Name: Janumet
Active Comparator: 2 pioglitazone	Drug: Comparator: pioglitazone pioglitazone 30 mg tablet qd, titrating up to 45 mg qd for an ~32-wk treatment period. Other Name: pioglitazone

Eligibility

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

Criteria

General Inclusion Criteria:

- Patient has type 2 diabetes mellitus
- Patient is inadequately controlled and not on treatment with insulin or oral antihyperglycemic therapy

General Exclusion Criteria:

- Patient has a history of type 1 diabetes mellitus or history of ketoacidosis
- Patient was on antihyperglycemic agent therapy (oral or insulin) within the prior 12 weeks
- Patient was on >4 weeks (cumulatively) of antihyperglycemic therapy (oral or insulin) over the prior 3 years

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: NCT00532935

Sponsors and Collaborators

Merck Sharp & Dohme Corp.

Investigators

Study Director: Medical Monitor Merck Sharp & Dohme Corp.

More Information

Publications:

Wainstein J, Katz L, Engel SS, Xu L, Golm GT, Hussain S, O'Neill EA, Kaufman KD, Goldstein BJ. Initial therapy with the fixed-dose combination of sitagliptin and metformin results in greater improvement in glycaemic control compared with pioglitazone monotherapy in patients with type 2 diabetes. Diabetes Obes Metab. 2012 May;14(5):409-18. doi: 10.1111/j.1463-1326.2011.01530.x. Epub 2011 Dec 22.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00532935 History of Changes
Other Study ID Numbers:	0431A-066 2007_510
Study First Received:	September 19, 2007
Results First Received:	September 23, 2010
Last Updated:	December 16, 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
Metformin	Molecular Mechanisms of Pharmacological Action
Pioglitazone	Pharmacologic Actions
Sitagliptin	Physiological Effects of Drugs
Dipeptidyl-Peptidase IV Inhibitors	Protease Inhibitors

ClinicalTrials.gov processed this record on April 13, 2016

TO TOP

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

HOME RSS FEEDS SITE MAP TERMS AND CONDITIONS DISCLAIMER CONTACT NLM HELP DESK

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History of Changes

Results First Received: September 23, 2010

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 (+) metformin hydrochloride Drug: Comparator: pioglitazone

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

First Patient In: 19-Mar-2008

Last Patient Last Visit: 23-Oct-2009

Seventy-four medical clinics worldwide (19 sites in the United States, 31 in Eastern Europe, and 24 in the rest of the world).

Pre-Assignment Details

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

Patients 18-78 years old with Type 2 Diabetes Mellitus (T2DM), drug-naïve (off antihyperglycemic agent [AHA] for at least 3 months prior to screening, and a maximum 4 weeks cumulative AHA therapy over the

previous 3 years), hemoglobin A1C 7.5 to 12% were eligible. Eligible patients underwent a 2-week placebo run-in period prior to randomization.

Reporting Groups

	Description
Sitagliptin/Metformin Fixed-Dose Combination	The Sitagliptin/Metformin Fixed-Dose Combination (Sita/Met FDC) group includes data from patients randomized to receive treatment with oral tablets of Sita/Met FDC initiated at a dose of 50/500 mg twice a day (b.i.d). The dose was to have been up-titrated over 4 weeks to 50/1000 mg b.i.d. Patients were discontinued if they were considered clinically inappropriate for up-titration or could not be up-titrated or maintained on the up-titrated dose.
Pioglitazone	The Pioglitazone group includes data from patients randomized to receive treatment with oral tablets of pioglitazone initiated at a dose of 30 mg once daily (q.d.). The dose was to have been up-titrated over 4 weeks to 45 mg q.d. Patients were discontinued if they were considered clinically inappropriate for up-titration or could not be up-titrated or maintained on the up-titrated dose.

Participant Flow: Overall Study

	Sitagliptin/Metformin Fixed-Dose Combination	Pioglitazone
STARTED	**261** [1]	**256** [1]
COMPLETED	**210**	**204**
NOT COMPLETED	**51**	**52**
Adverse Event	**11**	**12**
Lack of Efficacy	**0**	**3**
Lost to Follow-up	**10**	**6**
Physician Decision	**4**	**5**
Pregnancy	**1**	**0**
Protocol Violation	**4**	**2**
Withdrawal by Subject	**10**	**9**
Protocol Specific Criteria	**11**	**15**

[1] Excludes 1 patient who was randomized twice at different sites.

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/Metformin Fixed-Dose Combination	The Sitagliptin/Metformin Fixed-Dose Combination (Sita/Met FDC) group includes data from patients randomized to receive treatment with oral tablets of Sita/Met FDC initiated at a dose

	of 50/500 mg twice a day (b.i.d). The dose was to have been up-titrated over 4 weeks to 50/1000 mg b.i.d. Patients were discontinued if they were considered clinically inappropriate for up-titration or could not be up-titrated or maintained on the up-titrated dose.
Pioglitazone	The Pioglitazone group includes data from patients randomized to receive treatment with oral tablets of pioglitazone initiated at a dose of 30 mg once daily (q.d.). The dose was to have been up-titrated over 4 weeks to 45 mg q.d. Patients were discontinued if they were considered clinically inappropriate for up-titration or could not be up-titrated or maintained on the up-titrated dose.
Total	Total of all reporting groups

Baseline Measures

	Sitagliptin/Metformin Fixed-Dose Combination	Pioglitazone	Total
Number of Participants [units: participants]	**261**	**256**	**517**
Age [units: years] Mean (Standard Deviation)	**52.4 (10.7)**	**52.2 (11)**	**52.3 (10.8)**
Gender [units: participants]			
Female	**118**	**122**	**240**
Male	**143**	**134**	**277**
Race/Ethnicity, Customized [units: participants]			
White	**168**	**167**	**335**
Black	**6**	**5**	**11**
American Indian	**2**	**0**	**2**
Asian	**58**	**55**	**113**
Multi-racial	**27**	**29**	**56**
Hemoglobin A1C (A1C) [units: Percent of glycosylated hemoglobin (A1C)] Mean (Standard Deviation)	**9.0 (1.3)**	**8.9 (1.3)**	**8.9 (1.3)**
Fasting Plasma Glucose (FPG) [units: mg/dL] Mean (Standard Deviation)	**190.6 (53.4)**	**188.9 (57.1)**	**189.8 (55.2)**
2-Hour Post-Meal Glucose (2-HR PMG) [units: mg/dL] Mean (Standard Deviation)	**273.7 (84.8)**	**278.8 (86.4)**	**276.2 (85.5)**

Outcome Measures

Hide All Outcome Measures

1. Primary: Change From Baseline in A1C at Week 32 [Time Frame: Baseline and Week 32]

Measure Type	Primary
Measure Title	Change From Baseline in A1C at Week 32

Measure Description	A1C is measured as a percent. Thus this change from baseline reflects the Week 32 A1C percent minus the baseline A1C percent
Time Frame	Baseline and Week 32
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 Full Analysis Set (FAS) included all patients who received at least one dose of double-blind study drug and had both a baseline value and ≥ 1 post-baseline value for this outcome. For FAS patients with no data at Week 32, the last non-baseline observed measurement was carried forward to Week 32.

Reporting Groups

	Description
Sitagliptin/Metformin Fixed-Dose Combination	The Sitagliptin/Metformin Fixed-Dose Combination (Sita/Met FDC) group includes data from patients randomized to receive treatment with oral tablets of Sita/Met FDC initiated at a dose of 50/500 mg twice a day (b.i.d). The dose was to have been up-titrated over 4 weeks to 50/1000 mg b.i.d. Patients were discontinued if they were considered clinically inappropriate for up-titration or could not be up-titrated or maintained on the up-titrated dose.
Pioglitazone	The Pioglitazone group includes data from patients randomized to receive treatment with oral tablets of pioglitazone initiated at a dose of 30 mg once daily (q.d.). The dose was to have been up-titrated over 4 weeks to 45 mg q.d. Patients were discontinued if they were considered clinically inappropriate for up-titration or could not be up-titrated or maintained on the up-titrated dose.

Measured Values

	Sitagliptin/Metformin Fixed-Dose Combination	**Pioglitazone**
Number of Participants Analyzed [units: participants]	**253**	**246**
Change From Baseline in A1C at Week 32 [units: Percent of glycosylated hemoglobin (A1C)] Least Squares Mean (95% Confidence Interval)	**-1.86 (-2.00 to -1.73)**	**-1.39 (-1.53 to -1.26)**

Statistical Analysis 1 for Change From Baseline in A1C at Week 32

Groups [1]	All groups
Method [2]	ANCOVA
P Value [3]	<0.001
Mean Difference (Net) [4]	-0.47
Standard Deviation	(1.10)
95% Confidence Interval	-0.66 to -0.28

[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:

	ANCOVA model included a term for treatment and a covariate for the baseline A1C value.
[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 Fasting Plasma Glucose (FPG) at Week 1 [Time Frame: Baseline and Week 1]

Measure Type	Secondary
Measure Title	Change From Baseline in Fasting Plasma Glucose (FPG) at Week 1
Measure Description	Change from baseline reflects the Week 1 FPG minus the baseline FPG. At Week 1, the dose was 50/500 mg b.i.d. for Sita/Met FDC and 30 mg q.d. for pioglitazone
Time Frame	Baseline and Week 1
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 Full Analysis Set (FAS) included all patients who received at least one dose of double-blind study drug and had both a baseline value and ≥ 1 post-baseline value for this outcome.

Reporting Groups

	Description
Sitagliptin/Metformin Fixed-Dose Combination	The Sitagliptin/Metformin Fixed-Dose Combination (Sita/Met FDC) group includes data from patients randomized to receive treatment with oral tablets of Sita/Met FDC initiated at a dose of 50/500 mg twice a day (b.i.d). The dose was to have been up-titrated over 4 weeks to 50/1000 mg b.i.d. Patients were discontinued if they were considered clinically inappropriate for up-titration or could not be up-titrated or maintained on the up-titrated dose.
Pioglitazone	The Pioglitazone group includes data from patients randomized to receive treatment with oral tablets of pioglitazone initiated at a dose of 30 mg once daily (q.d.). The dose was to have been up-titrated over 4 weeks to 45 mg q.d. Patients were discontinued if they were considered clinically inappropriate for up-titration or could not be up-titrated or maintained on the up-titrated dose.

Measured Values

	Sitagliptin/Metformin Fixed-Dose Combination	**Pioglitazone**
Number of Participants Analyzed [units: participants]	**250**	**242**
Change From Baseline in Fasting Plasma Glucose (FPG) at Week 1 [units: mg/dL] Least Squares Mean (95% Confidence Interval)	**-40.5 (-44.1 to -36.9)**	**-13.0 (-16.6 to -9.3)**

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

Groups [1]	All groups
Method [2]	ANCOVA
P Value [3]	<0.001
Mean Difference (Net) [4]	-27.6
Standard Deviation	(29.1)
95% Confidence Interval	-32.7 to -22.4

[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:
	ANCOVA model included a term for treatment and a covariate for the baseline FPG value.
[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. Secondary: Change From Baseline in 2-hour Post-Meal Glucose (PMG) at Week 32 [Time Frame: Baseline and Week 32]

Measure Type	Secondary
Measure Title	Change From Baseline in 2-hour Post-Meal Glucose (PMG) at Week 32
Measure Description	Change from baseline reflects the Week 32 2-hour PMG minus the baseline 2-hour PMG
Time Frame	Baseline and Week 32
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 Full Analysis Set (FAS) included all patients who received at least one dose of double-blind study drug and had both a baseline value and ≥ 1 post-baseline value for this outcome. For FAS patients with no data at Week 32, the last non-baseline observed measurement was carried forward to Week 32.

Reporting Groups

	Description
Sitagliptin/Metformin Fixed-Dose Combination	The Sitagliptin/Metformin Fixed-Dose Combination (Sita/Met FDC) group includes data from patients randomized to receive treatment with oral tablets of Sita/Met FDC initiated at a dose of 50/500 mg twice a day (b.i.d). The dose was to have been up-titrated over 4 weeks to 50/1000 mg b.i.d. Patients were discontinued if they were considered clinically inappropriate for up-titration or could not be up-titrated or maintained on the up-titrated dose.
Pioglitazone	The Pioglitazone group includes data from patients randomized to receive treatment with oral tablets of pioglitazone initiated at a dose of 30 mg once daily (q.d.). The dose was to have

	been up-titrated over 4 weeks to 45 mg q.d. Patients were discontinued if they were considered clinically inappropriate for up-titration or could not be up-titrated or maintained on the up-titrated dose.

Measured Values

	Sitagliptin/Metformin Fixed-Dose Combination	Pioglitazone
Number of Participants Analyzed [units: participants]	**192**	**198**
Change From Baseline in 2-hour Post-Meal Glucose (PMG) at Week 32 [units: mg/dL] Least Squares Mean (95% Confidence Interval)	**-102.2 (-110.7 to -93.8)**	**-82.0 (-90.4 to -73.7)**

Statistical Analysis 1 for Change From Baseline in 2-hour Post-Meal Glucose (PMG) at Week 32

Groups [1]	All groups
Method [2]	ANCOVA
P Value [3]	<0.001
Mean Difference (Net) [4]	-20.2
Standard Deviation	(59.7)
95% Confidence Interval	-32.1 to -8.3

[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:
	ANCOVA model included a term for treatment and a covariate for the baseline 2-hour PMG value.
[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.

4. Secondary: Change From Baseline in FPG at Week 32 [Time Frame: Baseline and Week 32]

Measure Type	Secondary
Measure Title	Change From Baseline in FPG at Week 32
Measure Description	Change from baseline reflects the Week 32 FPG minus the baseline FPG
Time Frame	Baseline and Week 32
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) included all patients who received at least one dose of double-blind study drug and had both a baseline value and ≥ 1 post-baseline value for this outcome. For FAS patients with no data at Week 32, the last non-baseline observed measurement was carried forward to Week 32.

Reporting Groups

	Description
Sitagliptin/Metformin Fixed-Dose Combination	The Sitagliptin/Metformin Fixed-Dose Combination (Sita/Met FDC) group includes data from patients randomized to receive treatment with oral tablets of Sita/Met FDC initiated at a dose of 50/500 mg twice a day (b.i.d). The dose was to have been up-titrated over 4 weeks to 50/1000 mg b.i.d. Patients were discontinued if they were considered clinically inappropriate for up-titration or could not be up-titrated or maintained on the up-titrated dose.
Pioglitazone	The Pioglitazone group includes data from patients randomized to receive treatment with oral tablets of pioglitazone initiated at a dose of 30 mg once daily (q.d.). The dose was to have been up-titrated over 4 weeks to 45 mg q.d. Patients were discontinued if they were considered clinically inappropriate for up-titration or could not be up-titrated or maintained on the up-titrated dose.

Measured Values

	Sitagliptin/Metformin Fixed-Dose Combination	**Pioglitazone**
Number of Participants Analyzed [units: participants]	**258**	**250**
Change From Baseline in FPG at Week 32 [units: mg/dL] Least Squares Mean (95% Confidence Interval)	**-56.0 (-60.9 to -51.0)**	**-44.0 (-49.1 to -39.0)**

Statistical Analysis 1 for Change From Baseline in FPG at Week 32

Groups [1]	All groups
Method [2]	ANCOVA
P Value [3]	<0.001
Mean Difference (Net) [4]	-11.9
Standard Deviation	(40.3)
95% Confidence Interval	-19.0 to -4.9

[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:
	ANCOVA model included a term for treatment and a covariate for the baseline FPG value.
[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.

5. Secondary: Percent of Participants With A1C <7.0% at Week 32 [Time Frame: Week 32]

Measure Type	Secondary
Measure Title	Percent of Participants With A1C <7.0% at Week 32
Measure Description	No text entered.
Time Frame	Week 32
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 Full Analysis Set (FAS) included all patients who received at least one dose of double-blind study drug and had both a baseline value and ≥ 1 post-baseline value for this outcome. For FAS patients with no data at Week 32, the last non-baseline observed measurement was carried forward to Week 32.

Reporting Groups

	Description
Sitagliptin/Metformin Fixed-Dose Combination	The Sitagliptin/Metformin Fixed-Dose Combination (Sita/Met FDC) group includes data from patients randomized to receive treatment with oral tablets of Sita/Met FDC initiated at a dose of 50/500 mg twice a day (b.i.d). The dose was to have been up-titrated over 4 weeks to 50/1000 mg b.i.d. Patients were discontinued if they were considered clinically inappropriate for up-titration or could not be up-titrated or maintained on the up-titrated dose.
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Measured Values

	Sitagliptin/Metformin Fixed-Dose Combination	**Pioglitazone**
Number of Participants Analyzed [units: participants]	**253**	**246**
Percent of Participants With A1C <7.0% at Week 32 [units: Percent Participants]	**57.3**	**43.5**

Statistical Analysis 1 for Percent of Participants With A1C <7.0% at Week 32

Groups [1]	All groups
Method [2]	Regression, Logistic
P Value [3]	<0.001
Odds Ratio (OR) [4]	2.0
95% Confidence Interval	1.3 to 2.8

[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:
	logistic regression model included a term for treatment and a covariate for the baseline A1C value.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	Based on a test of the odds ratio = 1, comparing the odds of having A1C <7.0% at Week 32 in the Sitagliptin/Metformin 50/1000 mg b.i.d. group vs. the Pioglitazone 45 mg q.d. group.
[4]	Other relevant estimation information:
	This parameter estimate and 95% confidence interval correspond to the odds of having A1C <7.0% at Week 32 in the Sitagliptin/Metformin 50/1000 mg b.i.d. group vs. the Pioglitazone 45 mg q.d. group.

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	Week 0 through Week 32
Additional Description	No text entered.

Reporting Groups

	Description
Sitagliptin/Metformin Fixed-Dose Combination	The Sitagliptin/Metformin Fixed-Dose Combination (Sita/Met FDC) group includes data from patients randomized to receive treatment with oral tablets of Sita/Met FDC initiated at a dose of 50/500 mg twice a day (b.i.d). The dose was to have been up-titrated over 4 weeks to 50/1000 mg b.i.d. Patients were discontinued if they were considered clinically inappropriate for up-titration or could not be up-titrated or maintained on the up-titrated dose.
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Serious Adverse Events

	Sitagliptin/Metformin Fixed-Dose Combination	Pioglitazone
Total, serious adverse events		
# participants affected / at risk	**11/261 (4.21%)**	**8/256 (3.13%)**
Eye disorders		
Conjunctivitis allergic * 1		
# participants affected / at risk	**1/261 (0.38%)**	**0/256 (0.00%)**
Ulcerative keratitis * 1		
# participants affected / at risk	**1/261 (0.38%)**	**0/256 (0.00%)**

Gastrointestinal disorders		
Pancreatitis [*1]		
# participants affected / at risk	**1/261 (0.38%)**	**0/256 (0.00%)**
Upper gastrointestinal haemorrhage [*1]		
# participants affected / at risk	**0/261 (0.00%)**	**1/256 (0.39%)**
Hepatobiliary disorders		
Cholecystitis [*1]		
# participants affected / at risk	**1/261 (0.38%)**	**0/256 (0.00%)**
Cholelithiasis [*1]		
# participants affected / at risk	**3/261 (1.15%)**	**0/256 (0.00%)**
Hepatitis [*1]		
# participants affected / at risk	**1/261 (0.38%)**	**0/256 (0.00%)**
Infections and infestations		
Pharyngitis [*1]		
# participants affected / at risk	**0/261 (0.00%)**	**1/256 (0.39%)**
Pneumonia [*1]		
# participants affected / at risk	**0/261 (0.00%)**	**1/256 (0.39%)**
Injury, poisoning and procedural complications		
Femur fracture [*1]		
# participants affected / at risk	**1/261 (0.38%)**	**0/256 (0.00%)**
Musculoskeletal and connective tissue disorders		
Intervertebral disc protrusion [*1]		
# participants affected / at risk	**1/261 (0.38%)**	**0/256 (0.00%)**
Musculoskeletal chest pain [*1]		
# participants affected / at risk	**0/261 (0.00%)**	**1/256 (0.39%)**
Osteoarthritis [*1]		
# participants affected / at risk	**0/261 (0.00%)**	**1/256 (0.39%)**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Basal cell carcinoma [*1]		
# participants affected / at risk	**0/261 (0.00%)**	**1/256 (0.39%)**
Colon cancer [*1]		
# participants affected / at risk	**1/261 (0.38%)**	**0/256 (0.00%)**
Renal cancer [*1]		
# participants affected / at risk	**1/261 (0.38%)**	**0/256 (0.00%)**
Nervous system disorders		
Brain stem infarction [*1]		
# participants affected / at risk	**1/261 (0.38%)**	**0/256 (0.00%)**
Transient ischaemic attack [*1]		
# participants affected / at risk	**1/261 (0.38%)**	**0/256 (0.00%)**
Pregnancy, puerperium and perinatal conditions		

Abortion spontaneous complete * 1		
# participants affected / at risk	**1/261 (0.38%)**	**0/256 (0.00%)**
Renal and urinary disorders		
Urine flow decreased * 1		
# participants affected / at risk	**0/261 (0.00%)**	**1/256 (0.39%)**
Respiratory, thoracic and mediastinal disorders		
Chronic obstructive pulmonary disease * 1		
# participants affected / at risk	**1/261 (0.38%)**	**1/256 (0.39%)**

* Events were collected by non-systematic assessment

1 Term from vocabulary, MedDRA (12.1)

Other Adverse Events

Hide Other Adverse Events

Time Frame	Week 0 through Week 32
Additional Description	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Sitagliptin/Metformin Fixed-Dose Combination	The Sitagliptin/Metformin Fixed-Dose Combination (Sita/Met FDC) group includes data from patients randomized to receive treatment with oral tablets of Sita/Met FDC initiated at a dose of 50/500 mg twice a day (b.i.d). The dose was to have been up-titrated over 4 weeks to 50/1000 mg b.i.d. Patients were discontinued if they were considered clinically inappropriate for up-titration or could not be up-titrated or maintained on the up-titrated dose.
Pioglitazone	The Pioglitazone group includes data from patients randomized to receive treatment with oral tablets of pioglitazone initiated at a dose of 30 mg once daily (q.d.). The dose was to have been up-titrated over 4 weeks to 45 mg q.d. Patients were discontinued if they were considered clinically inappropriate for up-titration or could not be up-titrated or maintained on the up-titrated dose.

Other Adverse Events

	Sitagliptin/Metformin Fixed-Dose Combination	**Pioglitazone**
Total, other (not including serious) adverse events		
# participants affected / at risk	**94/261 (36.02%)**	**68/256 (26.56%)**
Gastrointestinal disorders		
Diarrhoea * 1		
# participants affected / at risk	**40/261 (15.33%)**	**11/256 (4.30%)**
Dyspepsia * 1		

# participants affected / at risk	**13/261 (4.98%)**	**2/256 (0.78%)**
General disorders		
Oedema peripheral * 1		
# participants affected / at risk	**3/261 (1.15%)**	**18/256 (7.03%)**
Infections and infestations		
Nasopharyngitis * 1		
# participants affected / at risk	**10/261 (3.83%)**	**16/256 (6.25%)**
Upper respiratory tract infection * 1		
# participants affected / at risk	**13/261 (4.98%)**	**17/256 (6.64%)**
Metabolism and nutrition disorders		
Hypoglycaemia * 1		
# participants affected / at risk	**22/261 (8.43%)**	**11/256 (4.30%)**
Nervous system disorders		
Headache * 1		
# participants affected / at risk	**20/261 (7.66%)**	**7/256 (2.73%)**

* Events were collected by non-systematic assessment
1 Term from vocabulary, MedDRA (12.1)

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

Unknown to the Sponsor and the investigators, two patients in the study were randomized twice (each at two different sites). Data for these patients were deemed unreliable and excluded from all analyses (efficacy and safety).

More Information

Hide More Information

Certain Agreements:

Principal Investigators are **NOT** employed by the organization sponsoring the study.

There **IS** an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

The agreement is:

☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **less than or equal to 60 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **more than 60 days but less than or equal to 180 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

☑ Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed.

Restriction Description: Merck agreements may vary with individual investigators, but will not prohibit any investigator from publishing. Merck supports the publication of results from all centers of a multi-center trial but requests that reports based on single-site data not precede the primary publication of the entire clinical trial.

Results Point of Contact:

Name/Title: Senior Vice President, Global Clinical Development
Organization: Merck Sharp & Dohme Corp
phone: 1-800-672-6372
e-mail: ClinicalTrialsDisclosure@merck.com

Publications of Results:

Wainstein J, Katz L, Engel SS, Xu L, Golm GT, Hussain S, O'Neill EA, Kaufman KD, Goldstein BJ. Initial therapy with the fixed-dose combination of sitagliptin and metformin results in greater improvement in glycaemic control compared with pioglitazone monotherapy in patients with type 2 diabetes. Diabetes Obes Metab. 2012 May;14(5):409-18. doi: 10.1111/j.1463-1326.2011.01530.x. Epub 2011 Dec 22.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00532935 History of Changes
Other Study ID Numbers:	0431A-066 2007_510
Study First Received:	September 19, 2007
Results First Received:	September 23, 2010
Last Updated:	December 16, 2015
Health Authority:	United States: Food and Drug Administration

TO TOP

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

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