Initial Combination With Pioglitazone Study (0431-064)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

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

ClinicalTrials.gov Identifier:
NCT00397631

First received: November 8, 2006
Last updated: January 27, 2015
Last verified: January 2015
History of Changes

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Purpose

A clinical study to evaluate the safety and efficacy of the initial combination therapy with sitagliptin and pioglitazone in patients with type 2 diabetes mellitus not on treatment with insulin or oral antihyperglycemic therapy.

Condition	Intervention	Phase
Type 2 Diabetes Mellitus	Drug: sitagliptin 100 mg q.d./pioglitazone 30 mg q.d Drug: Comparator: placebo to match sitagliptin 100 mg q.d./pioglitazone 30 mg q.d.	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 Multicenter, Randomized, Double-Blind Study to Evaluate the Safety and Efficacy of the Initial Therapy With Coadministration of Sitagliptin and Pioglitazone in Patients With Type 2 Diabetes Mellitus

Resource links provided by NLM:

MedlinePlus related topics: Diabetes Type 2

Drug Information available for: 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 HbA1c (Hemoglobin A1C) at Week 24 [Time Frame: Baseline and 24 weeks] [Designated as safety issue: No]
  HbA1c is measured as a percent. Thus, this change from baseline reflects the Week 24 HbA1c percent minus the Week 0 HbA1c percent.

Secondary Outcome Measures:

- Change From Baseline in FPG (Fasting Plasma Glucose) at Week 24 [Time Frame: Baseline and Week 24] [Designated as safety issue: No]
  Change from baseline at Week 24 is defined as Week 24 minus Week 0.

- Change From Baseline in 2-hour PPG (Post-prandial Glucose) at Week 24 [Time Frame: Baseline and Week 24]
  [Designated as safety issue: No]
  Change from baseline at Week 24 is defined as Week 24 minus Week 0.

Enrollment:	520
Study Start Date:	December 2006
Study Completion Date:	June 2008
Primary Completion Date:	June 2008 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: 1 sitagliptin 100 mg q.d./pioglitazone 30 mg q.d.	Drug: sitagliptin 100 mg q.d./pioglitazone 30 mg q.d Patients will receive initial combination therapy with blinded sitagliptin 100 mg q.d. and open- label pioglitazone 30 mg q.d. for up to 24 Weeks. Sitagliptin 100 mg q.d. and pioglitazone 30 mg q.d. will be administered as oral tablets.
Active Comparator: 2 sitagliptin 100 mg placebo q.d./pioglitazone 30 mg q.d.	Drug: Comparator: placebo to match sitagliptin 100 mg q.d./pioglitazone 30 mg q.d. Patients will receive placebo to match sitagliptin 100 mg q.d. (blinded) and open label pioglitazone 30 mg q.d. for up to 24 Weeks. Placebo to match sitagliptin 100 mg q.d.(blinded) and open-label pioglitazone 30 mg q.d. will be administered as oral tablets.

Eligibility

Ages Eligible for Study:	18 Years and older
Genders Eligible for Study:	Both
Accepts Healthy Volunteers:	No

Criteria

General Inclusion Criteria:

- Patients ≥18 years old with Type 2 Diabetes Mellitus (a specific type of diabetes)

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 4 months
- Patient was on >4 weeks (cumulatively) of antihyperglycemic therapy (oral or insulin) over the prior 2 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: NCT00397631

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 EXIT

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

Publications:

Yoon KH, Shockey GR, Teng R, Golm GT, Thakkar PR, Meehan AG, Williams-Herman DE, Kaufman KD, Amatruda JM, Steinberg H. Effect of initial combination therapy with sitagliptin, a dipeptidyl peptidase-4 inhibitor, and pioglitazone on glycemic control and measures of β-cell function in patients with type 2 diabetes. Int J Clin Pract. 2011 Feb;65(2):154-64. doi: 10.1111/j.1742-1241.2010.02589.x.

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Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00397631 History of Changes
Other Study ID Numbers:	0431-064 MK0431-064 2006_531
Study First Received:	November 8, 2006
Results First Received:	May 19, 2009
Last Updated:	January 27, 2015
Health Authority:	United States: Food and Drug Administration

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
Pioglitazone	Pharmacologic Actions
Sitagliptin	Physiological Effects of Drugs
Dipeptidyl-Peptidase IV Inhibitors	Protease Inhibitors
Enzyme Inhibitors	

ClinicalTrials.gov processed this record on April 13, 2016

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Results First Received: May 19, 2009

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 100 mg q.d./pioglitazone 30 mg q.d Drug: Comparator: placebo to match sitagliptin 100 mg q.d./pioglitazone 30 mg q.d.

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: 01-Feb-2007; Last Patient Last Visit: 28-Jun-2008; 60 study sites worldwide.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
Patients ≥18 years of age with type 2 diabetes mellitus (T2DM) with inadequate glycemic control (HbA1C ≥8% and ≤12%) on diet and exercise alone were eligible for randomization.

Reporting Groups

	Description
Sitagliptin 100 mg q.d. + Pioglitazone 30 mg q.d.	The Sitagliptin 100 mg q.d. + Pioglitazone 30 mg q.d. (q.d. = once daily) group includes data from patients randomized to receive coadministration of sitagliptin 100 mg oral tablets and pioglitazone 30 mg oral tablets administered once daily.
Pioglitazone 30 mg q.d.	The Pioglitazone 30 mg q.d. (q.d. = once daily) group includes data from patients randomized to receive coadministration of pioglitazone 30 mg oral tablets and placebo to sitagliptin 100 mg oral tablets administered once daily.

Participant Flow: Overall Study

	Sitagliptin 100 mg q.d. + Pioglitazone 30 mg q.d.	Pioglitazone 30 mg q.d.
STARTED	**261** [1]	**259**
COMPLETED	**231**	**215**
NOT COMPLETED	**30**	**44**
Adverse Event	**5**	**6**
Lack of Efficacy	**7**	**10**
Lost to Follow-up	**8**	**9**
Physician Decision	**2**	**0**
Protocol Violation	**0**	**1**
Withdrawal by Subject	**7**	**14**
protocol discontinuation criteria	**1**	**4**

[1] Randomization ratio was 1:1

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 100 mg q.d. + Pioglitazone 30 mg q.d.	The Sitagliptin 100 mg q.d. + Pioglitazone 30 mg q.d. (q.d. = once daily) group includes data from patients randomized to receive coadministration of sitagliptin 100 mg oral tablets and pioglitazone 30 mg oral tablets administered once daily.
Pioglitazone 30 mg q.d.	The Pioglitazone 30 mg q.d. (q.d. = once daily) group includes data from patients randomized to receive coadministration of pioglitazone 30 mg oral tablets and placebo to sitagliptin 100 mg oral tablets administered once daily.
Total	Total of all reporting groups

Baseline Measures

	Sitagliptin 100 mg q.d. + Pioglitazone 30 mg q.d.	Pioglitazone 30 mg q.d.	Total

Number of Participants [units: participants]	**261**	**259**	**520**
Age [units: years] Mean (Standard Deviation)	**50.2 (10.2)**	**51.6 (11.2)**	**50.9 (10.7)**
Gender [units: participants]			
Female	**124**	**114**	**238**
Male	**137**	**145**	**282**
Race/Ethnicity, Customized [units: participants]			
White	**138**	**134**	**272**
Black	**11**	**8**	**19**
Asian	**85**	**83**	**168**
Other	**27**	**34**	**61**
HbA1c (Hemoglobin A1C) [units: Percent] Mean (Standard Deviation)	**9.5 (1.2)**	**9.5 (1.2)**	**9.5 (1.2)**

Outcome Measures

Hide All Outcome Measures

1. Primary: Change From Baseline in HbA1c (Hemoglobin A1C) at Week 24 [Time Frame: Baseline and 24 weeks]

Measure Type	Primary
Measure Title	Change From Baseline in HbA1c (Hemoglobin A1C) at Week 24
Measure Description	HbA1c is measured as a percent. Thus, this change from baseline reflects the Week 24 HbA1c percent minus the Week 0 HbA1c percent.
Time Frame	Baseline and 24 weeks
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The Full Analysis Set (FAS) included all patients with a baseline value and ≥1 post-baseline value for this outcome. For FAS patients with no data at Week 24, the last observed measurement was carried forward to Week 24.

Reporting Groups

	Description
Sitagliptin 100 mg q.d. + Pioglitazone 30 mg q.d.	The Sitagliptin 100 mg q.d. + Pioglitazone 30 mg q.d. (q.d. = once daily) group includes data from patients randomized to receive coadministration of sitagliptin 100 mg oral tablets and pioglitazone 30 mg oral tablets administered once daily.
Pioglitazone 30 mg q.d.	The Pioglitazone 30 mg q.d. (q.d. = once daily) group includes data from patients randomized to receive coadministration of pioglitazone 30 mg oral tablets and placebo to

	sitagliptin 100 mg oral tablets administered once daily.

Measured Values

	Sitagliptin 100 mg q.d. + Pioglitazone 30 mg q.d.	Pioglitazone 30 mg q.d.
Number of Participants Analyzed [units: participants]	**251**	**246**
Change From Baseline in HbA1c (Hemoglobin A1C) at Week 24 [units: Percent] Least Squares Mean (95% Confidence Interval)	**-2.38 (-2.55 to -2.21)**	**-1.49 (-1.66 to -1.32)**

Statistical Analysis 1 for Change From Baseline in HbA1c (Hemoglobin A1C) at Week 24

Groups [1]	All groups
Method [2]	ANCOVA
P Value [3]	<0.001
Mean Difference (Net) [4]	-0.89
Standard Error of the mean	(0.12)
95% Confidence Interval	-1.13 to -0.65

[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:
	Model terms: treatment, baseline HbA1c
[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 FPG (Fasting Plasma Glucose) at Week 24 [Time Frame: Baseline and Week 24]

Measure Type	Secondary
Measure Title	Change From Baseline in FPG (Fasting Plasma Glucose) at Week 24
Measure Description	Change from baseline at Week 24 is defined as Week 24 minus Week 0.
Time Frame	Baseline and Week 24
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or

another method. Also provides relevant details such as imputation technique, as appropriate.
The Full Analysis Set (FAS) included all patients with a baseline value and ≥1 post-baseline value for this outcome. For FAS patients with no data at Week 24, the last observed measurement was carried forward to Week 24.

Reporting Groups

	Description
Sitagliptin 100 mg q.d. + Pioglitazone 30 mg q.d.	The Sitagliptin 100 mg q.d. + Pioglitazone 30 mg q.d. (q.d. = once daily) group includes data from patients randomized to receive coadministration of sitagliptin 100 mg oral tablets and pioglitazone 30 mg oral tablets administered once daily.
Pioglitazone 30 mg q.d.	The Pioglitazone 30 mg q.d. (q.d. = once daily) group includes data from patients randomized to receive coadministration of pioglitazone 30 mg oral tablets and placebo to sitagliptin 100 mg oral tablets administered once daily.

Measured Values

	Sitagliptin 100 mg q.d. + Pioglitazone 30 mg q.d.	**Pioglitazone 30 mg q.d.**
Number of Participants Analyzed [units: participants]	**256**	**253**
Change From Baseline in FPG (Fasting Plasma Glucose) at Week 24 [units: mg/dL] Least Squares Mean (95% Confidence Interval)	**-63.0 (-68.3 to -57.6)**	**-40.2 (-45.6 to -34.8)**

Statistical Analysis 1 for Change From Baseline in FPG (Fasting Plasma Glucose) at Week 24

Groups [1]	All groups
Method [2]	ANCOVA
P Value [3]	<0.001
Mean Difference (Net) [4]	-22.8
Standard Error of the mean	(3.87)
95% Confidence Interval	-30.4 to -15.2

[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:
	Model terms: treatment, baseline FPG
[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 PPG (Post-prandial Glucose) at Week 24 [Time Frame: Baseline and Week 24]

Measure Type	Secondary
Measure Title	Change From Baseline in 2-hour PPG (Post-prandial Glucose) at Week 24
Measure Description	Change from baseline at Week 24 is defined as Week 24 minus Week 0.
Time Frame	Baseline and Week 24
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The Full Analysis Set (FAS) included all patients with a baseline value and ≥1 post-baseline value for this outcome. For FAS patients with no data at Week 24, the last observed measurement was carried forward to Week 24.

Reporting Groups

	Description
Sitagliptin 100 mg q.d. + Pioglitazone 30 mg q.d.	The Sitagliptin 100 mg q.d. + Pioglitazone 30 mg q.d. (q.d. = once daily) group includes data from patients randomized to receive coadministration of sitagliptin 100 mg oral tablets and pioglitazone 30 mg oral tablets administered once daily.
Pioglitazone 30 mg q.d.	The Pioglitazone 30 mg q.d. (q.d. = once daily) group includes data from patients randomized to receive coadministration of pioglitazone 30 mg oral tablets and placebo to sitagliptin 100 mg oral tablets administered once daily.

Measured Values

	Sitagliptin 100 mg q.d. + Pioglitazone 30 mg q.d.	**Pioglitazone 30 mg q.d.**
Number of Participants Analyzed [units: participants]	**216**	**211**
Change From Baseline in 2-hour PPG (Post-prandial Glucose) at Week 24 [units: mg/dL] Least Squares Mean (95% Confidence Interval)	**-113.6 (-122.4 to -104.8)**	**-68.9 (-77.8 to -60.0)**

Statistical Analysis 1 for Change From Baseline in 2-hour PPG (Post-prandial Glucose) at Week 24

Groups [1]	All groups
Method [2]	ANCOVA
P Value [3]	<0.001
Mean Difference (Net) [4]	-44.7
Standard Error of the mean	(6.37)
95% Confidence Interval	-57.2 to 32.2

[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:
	Model terms: treatment, baseline 2-hour PPG

[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	No text entered.
Additional Description	No text entered.

Reporting Groups

	Description
Sitagliptin 100 mg q.d. + Pioglitazone 30 mg q.d.	The Sitagliptin 100 mg q.d. + Pioglitazone 30 mg q.d. (q.d. = once daily) group includes data from patients randomized to receive coadministration of sitagliptin 100 mg oral tablets and pioglitazone 30 mg oral tablets administered once daily.
Pioglitazone 30 mg q.d.	The Pioglitazone 30 mg q.d. (q.d. = once daily) group includes data from patients randomized to receive coadministration of pioglitazone 30 mg oral tablets and placebo to sitagliptin 100 mg oral tablets administered once daily.

Serious Adverse Events

	Sitagliptin 100 mg q.d. + Pioglitazone 30 mg q.d.	Pioglitazone 30 mg q.d.
Total, serious adverse events		
# participants affected	**8**	**5**
Ear and labyrinth disorders		
Any Ear and labyrinth disorders [*1]		
# participants affected / at risk	**1/261 (0.38%)**	**0/259 (0.00%)**
Acute vestibular syndrome [*1]		
# participants affected / at risk	**1/261 (0.38%)**	**0/259 (0.00%)**
Gastrointestinal disorders		
Any Gastrointestinal disorders [*1]		
# participants affected / at risk	**2/261 (0.77%)**	**0/259 (0.00%)**
Abdominal pain upper [*1]		
# participants affected / at risk	**1/261 (0.38%)**	**0/259 (0.00%)**
Peptic ulcer [*1]		
# participants affected / at risk	**1/261 (0.38%)**	**0/259 (0.00%)**
Infections and infestations		
Any Infections and infestations [*1]		

# participants affected / at risk	2/261 (0.77%)	1/259 (0.39%)
Abscess limb * 1		
# participants affected / at risk	0/261 (0.00%)	1/259 (0.39%)
Bronchitis bacterial * 1		
# participants affected / at risk	1/261 (0.38%)	0/259 (0.00%)
Pulmonary tuberculosis * 1		
# participants affected / at risk	1/261 (0.38%)	0/259 (0.00%)
Injury, poisoning and procedural complications		
Any Injury, poisoning and procedural complications * 1		
# participants affected / at risk	1/261 (0.38%)	1/259 (0.39%)
Foreign body trauma * 1		
# participants affected / at risk	0/261 (0.00%)	1/259 (0.39%)
Humerus fracture * 1		
# participants affected / at risk	1/261 (0.38%)	0/259 (0.00%)
Nervous system disorders		
Any Nervous system disorders * 1		
# participants affected / at risk	0/261 (0.00%)	2/259 (0.77%)
Cerebrovascular accident * 1		
# participants affected / at risk	0/261 (0.00%)	1/259 (0.39%)
Transient ischaemic attack * 1		
# participants affected / at risk	0/261 (0.00%)	1/259 (0.39%)
Psychiatric disorders		
Any Psychiatric disorders * 1		
# participants affected / at risk	1/261 (0.38%)	0/259 (0.00%)
Impulsive behaviour * 1		
# participants affected / at risk	1/261 (0.38%)	0/259 (0.00%)
Skin and subcutaneous tissue disorders		
Any Skin and subcutaneous tissue disorders * 1		
# participants affected / at risk	1/261 (0.38%)	0/259 (0.00%)
Pustular psoriasis * 1		
# participants affected / at risk	1/261 (0.38%)	0/259 (0.00%)
Vascular disorders		
Any Vascular disorders * 1		
# participants affected / at risk	0/261 (0.00%)	1/259 (0.39%)
Peripheral ischaemia * 1		
# participants affected / at risk	0/261 (0.00%)	1/259 (0.39%)

* Events were collected by non-systematic assessment

1 Term from vocabulary, MedDRA 11.0

Other Adverse Events

Hide Other Adverse Events

Time Frame	No text entered.
Additional Description	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Sitagliptin 100 mg q.d. + Pioglitazone 30 mg q.d.	The Sitagliptin 100 mg q.d. + Pioglitazone 30 mg q.d. (q.d. = once daily) group includes data from patients randomized to receive coadministration of sitagliptin 100 mg oral tablets and pioglitazone 30 mg oral tablets administered once daily.
Pioglitazone 30 mg q.d.	The Pioglitazone 30 mg q.d. (q.d. = once daily) group includes data from patients randomized to receive coadministration of pioglitazone 30 mg oral tablets and placebo to sitagliptin 100 mg oral tablets administered once daily.

Other Adverse Events

	Sitagliptin 100 mg q.d. + Pioglitazone 30 mg q.d.	Pioglitazone 30 mg q.d.
Total, other (not including serious) adverse events		
# participants affected	**17**	**25**
Infections and infestations		
Any Infections and infestations [* 1]		
# participants affected / at risk	**8/261 (3.07%)**	**14/259 (5.41%)**
Nasopharyngitis [* 1]		
# participants affected / at risk	**8/261 (3.07%)**	**14/259 (5.41%)**
Nervous system disorders		
Any Nervous system disorders [* 1]		
# participants affected / at risk	**9/261 (3.45%)**	**13/259 (5.02%)**
Headache [* 1]		
# participants affected / at risk	**9/261 (3.45%)**	**13/259 (5.02%)**

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1 Term from vocabulary, MedDRA 11.0

Limitations and Caveats

Hide Limitations and Caveats

Limitations of the study, such as early termination leading to small numbers of participants analyzed and technical problems with measurement leading to unreliable or uninterpretable data
No text entered.

More Information

Hide More Information

Certain Agreements:

Principal Investigators are **NOT** employed by the organization sponsoring the study.
There **IS** an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.
The agreement is: ☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **less than or equal to 60 days**. The sponsor cannot require changes to the communication and cannot extend the embargo. ☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **more than 60 days but less than or equal to 180 days**. The sponsor cannot require changes to the communication and cannot extend the embargo. Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed. ☑ **Restriction Description:** 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:

Yoon KH, Shockey GR, Teng R, Golm GT, Thakkar PR, Meehan AG, Williams-Herman DE, Kaufman KD, Amatruda JM, Steinberg H. Effect of initial combination therapy with sitagliptin, a dipeptidyl peptidase-4 inhibitor, and pioglitazone on glycemic control and measures of β-cell function in patients with type 2 diabetes. Int J Clin Pract. 2011 Feb;65(2):154-64. doi: 10.1111/j.1742-1241.2010.02589.x.

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