ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
Release Date: May 8, 2015

ClinicalTrials.gov ID: NCT00683657

Study Identification

Unique Protocol ID:	CV181-066
Brief Title:	Safety and Efficacy Study of Subjects That Are Taking Saxagliptin Added Onto Metformin XR Compared to Subjects Taking Metformin XR Alone
Official Title:	A 4-Week, Multicenter, Randomized, Double-Blind, Placebo-Controlled Phase 3 Trial To Evaluate The Efficacy And Safety Of Saxagliptin In Comparison To Placebo As Add On Treatment To Metformin XR In Subjects With Type 2 Diabetes Who Have Inadequate Glycemic Control With Diet And Exercise And A Stable Dose Of Metformin ≥1500 mg/Day
Secondary IDs:	Eudract-2008-000976-26

Study Status

Record Verification:	May 2015
Overall Status:	Completed
Study Start:	July 2008
Primary Completion:	February 2009 [Actual]
Study Completion:	February 2009 [Actual]

Sponsor/Collaborators

Sponsor:	AstraZeneca
Responsible Party:	Sponsor
Collaborators:	AstraZeneca

Oversight

FDA Regulated?:	Yes
Applicable Trial?:	Section 801 Clinical Trial? Yes Delayed Posting? No
IND/IDE Protocol?:	Yes
IND/IDE Information:	Grantor: CDER IND/IDE Number: 63,634 Serial Number: 0267 Has Expanded Access? No
Review Board:	Approval Status: Board Name: Board Affiliation: Phone: Email:
Data Monitoring?:	No
Plan to Share IPD?:	
Oversight Authorities:	Argentina: Administracion Nacional de Medicamentos, Alimentos y Tecnologia Medica Italy: The Italian Medicines Agency United States: Food and Drug Administration Sweden: Medical Products Agency Sweden: Regional Ethical Review Board Finland: Finnish Medicines Agency Finland: Sub-Committee on Medical Research Ethics (TUKIJA) Israel: Ministry of Health Philippines: Bureau of Food and Drugs Philippines: National Ethics Committee Poland: Cental Evidence of Clinical Research

Study Description

Brief Summary:	This protocol will compare 24 hour glucose control for subject taking saxagliptin and metformin extended release (XR) versus metformin XR alone
Detailed Description:	

Conditions

Conditions:	Type 2 Diabetes

Keywords:

Study Design

Study Type: Interventional
Primary Purpose: Treatment
Study Phase: Phase 3
Intervention Model: Parallel Assignment
Number of Arms: 2
Masking: Double Blind (Subject, Investigator)
Allocation: Randomized
Endpoint Classification: Safety/Efficacy Study
Enrollment: 93 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: Saxagliptin 5 mg + Metformin	Drug: Saxagliptin Tablets, Oral, 5mg, once daily, 4 weeks Other Names: • BMS-477118
Placebo Comparator: Placebo + Metformin	Drug: Placebo Tablets, Oral, 0 mg, once daily, 4 weeks

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age: 18 Years
Maximum Age: 77 Years
Gender: Both
Accepts Healthy Volunteers?: No

Criteria: Inclusion Criteria:

- ≥18- and ≤77-years-old
- Type 2 diabetes
- Taking metformin immediate release (IR) or XR ≥1500 mg for at least 8 weeks as monotherapy
- Glycosylated hemoglobin (A1C) ≥7% and ≤10%
- Body mass index (BMI) ≤40 kg/m2

Exclusion Criteria:

- Women of childbearing potential unable or unwilling to use acceptable birth control
- Women who are pregnant or breastfeeding
- Significant cardiovascular history
- Active liver disease
- Renal impairment

Contacts/Locations

Study Officials: Bristol-Myers Squibb
Study Director
Bristol-Myers Squibb

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References

Citations:

Links: URL: http://ctr.bms.com/ctd/start.do
Description BMS Clinical Trials Disclosure

URL: http://www.bms.com/clinical_trials/Pages/Investigator_Inquiry_form.aspx
Description Investigator Inquiry form

URL: http://www.fda.gov/MEDWATCH/safety.htm
Description For FDA Safety Alerts and Recalls refer to the following link: http://www.fda.gov/MEDWATCH/safety.htm

URL: http://www.clinicalstudyresults.org/drugdetails/?company_id=4&drug_name_id=1235&sort=c.c...
Description CSR synopsis, posted to PhRMA website

Study Data/Documents:

Study Results

Participant Flow

Pre-Assignment Details	218 subjects were enrolled and 128 entered the 4-week dietary and exercise, and metformin extended release (XR) lead-in period. Thirty-five subjects did not enter treatment period (21 no longer met study criteria, 7 withdrew consent, 7 for poor protocol compliance).

Reporting Groups

	Description
Saxagliptin 5 mg + Metformin	Saxagliptin tablets, 5 mg, taken orally once daily for 4 weeks, plus metformin XR.
Placebo + Metformin	Placebo tablets, taken orally once daily for 4 weeks, plus metformin XR.

Overall Study

	Saxagliptin 5 mg + Metformin	Placebo + Metformin
Started	46	47
Randomized Subjects Data Set	46 [1]	47 [1]
Completed	45	46
Not Completed	1	1
Adverse Event	0	1
Subject Withdrew Consent	1	0

[1] Randomized subjects who took at least 1 dose of double-blind study medication.

Baseline Characteristics

Reporting Groups

	Description
Saxagliptin 5 mg + Metformin	Saxagliptin tablets, 5 mg, taken orally once daily for 4 weeks, plus metformin XR.
Placebo + Metformin	Placebo tablets, taken orally once daily for 4 weeks, plus metformin XR.

Baseline Measures

		Saxagliptin 5 mg + Metformin	Placebo + Metformin	Total
Overall Number of Participants		46	47	93
Age, Continuous Mean (Standard Deviation) Unit of measure: years	Number Analyzed	46 participants	47 participants	93 participants
		54.50 (9.20)	55.77 (9.14)	55.14 (9.14)
Age, Customized Measure Type: Number Unit of measure: participants	Number Analyzed	46 participants	47 participants	93 participants
<65 years		40	38	78
>= 65 years to <75 years		6	8	14
>= 75 years		0	1	1
Gender, Male/ Female Measure Type: Count of Participants Unit of measure: participants	Number Analyzed	46 participants	47 participants	93 participants
	Female	20 43.48%	24 51.06%	44 47.31%
	Male	26 56.52%	23 48.94%	49 52.69%
Race/Ethnicity, Customized Measure Type: Number Unit of measure: Participants	Number Analyzed	46 participants	47 participants	93 participants

		Saxagliptin 5 mg + Metformin	Placebo + Metformin	Total
White		39	43	82
Black/African American		3	2	5
Asian		2	1	3
Other		2	1	3

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Change From Baseline in 24-Hour Mean Weighted Glucose (MWG) at Week 4
Measure Description	Adjusted mean change from baseline in MWG achieved with saxagliptin 5 mg plus metformin XR versus placebo plus metformin XR at Week 24. MWG was calculated as the area under the curve (AUC) for the full 24 hours expressed as average mg/dL. Glucose measurements were collected 30 minutes before and just prior to each meal (0 minutes) and 30, 60, 120, and 180 minutes after each meal (with 1 additional measurement at 240 minutes after the evening meal), midnight, 3 AM, and at end-of-domicile visit 24 hours after the first measurement. Mean change from baseline was adjusted for baseline value.
Time Frame	Baseline, Week 4
Safety Issue?	No

Analysis Population Description

Randomized participants who took at least 1 dose of double-blind treatment. To be included in an analysis of change from baseline to Week 4 the subject must have had a baseline and a Week 4 measurement.

Reporting Groups

	Description
Saxagliptin 5 mg + Metformin	Saxagliptin tablets, 5 mg, taken orally once daily for 4 weeks, plus metformin XR.
Placebo + Metformin	Placebo tablets, taken orally once daily for 4 weeks, plus metformin XR.

Measured Values

	Saxagliptin 5 mg + Metformin	Placebo + Metformin
Number of Participants Analyzed	41	44
Change From Baseline in 24-Hour Mean Weighted Glucose (MWG) at Week 4 Mean (Standard Error) Unit of measure: mg/dL		

	Saxagliptin 5 mg + Metformin	Placebo + Metformin
Baseline Mean	177.5 (4.99)	181.2 (6.30)
Week 4 Mean	163.8 (5.09)	184.2 (7.05)
Adjusted Mean Change from Baseline	-13.8 (2.99)	3.0 (2.89)

Statistical Analysis 1 for Change From Baseline in 24-Hour Mean Weighted Glucose (MWG) at Week 4

Statistical Analysis Overview	Comparison Groups	Saxagliptin 5 mg + Metformin, Placebo + Metformin
	Comments	With 39 subjects per treatment group, there was a 93% power for the primary endpoint to detect a difference in 24-hour mean weighted glucose of 16 mg/dL between saxagliptin and placebo, assuming a standard deviation of 20 mg/dL. Assuming a dropout rate of 15%, a total of 92 subjects (46 subjects per treatment arm) needed to be randomized.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0001
	Comments	Between-group comparisons significant at alpha = 0.05, significance testing based on hierarchical testing. Primary and secondary endpoints are presented in order of testing.
	Method	ANCOVA
	Comments	ANCOVA Model: post - pre = pre treatment

Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	-16.8
	Confidence Interval	(2-Sided) 95% -25.1 to -8.5
	Parameter Dispersion	Type: Standard Error of the mean Value: 4.16
	Estimation Comments	Mean difference = adjusted mean change for saxagliptin 5 mg + Metformin - adjusted mean change for Placebo + Metformin.

2. Secondary Outcome Measure:

Measure Title	Change From Baseline in 4-Hour Mean Weighted Postprandial Plasma Glucose at Week 4

Measure Description	Adjusted mean change from baseline in 4-hour mean weighted postprandial (after mealtime) plasma glucose after the evening meal during 24-hour domicile visits evaluated both at pre-randomization (baseline) and at Week 4. Mean change from baseline was adjusted for baseline value.
Time Frame	Baseline, Week 4
Safety Issue?	No

Analysis Population Description

Randomized participants who took at least 1 dose of double-blind treatment. To be included in an analysis of change from baseline to Week 4 the subject must have had a baseline and a Week 4 measurement.

Reporting Groups

	Description
Saxagliptin 5 mg + Metformin	Saxagliptin tablets, 5 mg, taken orally once daily for 4 weeks, plus metformin XR.
Placebo + Metformin	Placebo tablets, taken orally once daily for 4 weeks, plus metformin XR.

Measured Values

	Saxagliptin 5 mg + Metformin	Placebo + Metformin
Number of Participants Analyzed	40	44
Change From Baseline in 4-Hour Mean Weighted Postprandial Plasma Glucose at Week 4 Mean (Standard Error) Unit of measure: mg/dL		
Baseline Mean	212.1 (6.80)	211.1 (6.60)
Week 4 Mean	181.4 (6.79)	210.8 (8.02)
Adjusted Mean Change from Baseline	-30.7 (5.14)	-0.4 (4.90)

Statistical Analysis 1 for Change From Baseline in 4-Hour Mean Weighted Postprandial Plasma Glucose at Week 4

Statistical Analysis Overview	Comparison Groups	Saxagliptin 5 mg + Metformin, Placebo + Metformin
	Comments	With 39 subjects per treatment group, there was a 93% power for the primary endpoint to detect a difference in 24-hour mean weighted glucose of 16 mg/dL between saxagliptin and placebo, assuming a standard deviation of 20 mg/dL. Assuming a dropout rate of 15%, a total of 92 subjects (46 subjects per treatment arm) needed to be randomized.
	Non-Inferiority or Equivalence Analysis?	No

	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	<0.0001
	Comments	Between-group comparisons significant at alpha = 0.05, significance testing based on hierarchical testing. Primary and secondary endpoints are presented in order of testing.
	Method	ANCOVA
	Comments	ANCOVA model: post - pre = pretreatment

Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	-30.2
	Confidence Interval	(2-Sided) 95% -44.4 to -16.1
	Parameter Dispersion	Type: Standard Error of the mean Value: 7.10
	Estimation Comments	Mean difference = adjusted mean change for saxagliptin 5 mg + Metformin - adjusted mean change for Placebo + Metformin

3. Secondary Outcome Measure:

Measure Title	Change From Baseline in 2-Hour Postprandial Plasma Glucose After the Evening Meal at Week 4
Measure Description	Adjusted mean change from baseline in 2-hour postprandial plasma glucose after the evening meal during 24-hour domicile visits, evaluated both at pre-randomization (baseline) and at Week 4. Mean change from baseline was adjusted for baseline value.
Time Frame	Baseline, Week 4
Safety Issue?	No

Analysis Population Description

Randomized participants who took at least 1 dose of double-blind treatment. To be included in an analysis of change from baseline to Week 4 the subject must have had a baseline and a Week 4 measurement.

Reporting Groups

	Description
Saxagliptin 5 mg + Metformin	Saxagliptin tablets, 5 mg, taken orally once daily for 4 weeks, plus metformin XR.
Placebo + Metformin	Placebo tablets, taken orally once daily for 4 weeks, plus metformin XR.

Measured Values

	Saxagliptin 5 mg + Metformin	Placebo + Metformin
Number of Participants Analyzed	41	44
Change From Baseline in 2-Hour Postprandial Plasma Glucose After the Evening Meal at Week 4 Mean (Standard Error) Unit of measure: mg/dL		
Baseline Mean	237.6 (8.87)	233.1 (7.74)
Week 4 Mean	198.5 (8.82)	231.1 (9.22)
Adjusted Change from Baseline	-38.2 (7.49)	-2.8 (7.23)

Statistical Analysis 1 for Change From Baseline in 2-Hour Postprandial Plasma Glucose After the Evening Meal at Week 4

Statistical Analysis Overview	Comparison Groups	Saxagliptin 5 mg + Metformin, Placebo + Metformin
	Comments	With 39 subjects per treatment group, there was a 93% power for the primary endpoint to detect a difference in 24-hour mean weighted glucose of 16 mg/dL between saxagliptin and placebo, assuming a standard deviation of 20 mg/dL. Assuming a dropout rate of 15%, a total of 92 subjects (46 subjects per treatment arm) needed to be randomized.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0010
	Comments	Between-group comparisons significant at alpha = 0.05, significance testing based on hierarchical testing. Primary and secondary endpoints are presented in order of testing.
	Method	ANCOVA
	Comments	ANCOVA model: post - pre = pretreatment

Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	-35.4
	Confidence Interval	(2-Sided) 95% -56.2 to -14.7
	Parameter Dispersion	Type: Standard Error of the mean Value: 10.41

	Estimation Comments	Mean difference = adjusted mean change for saxagliptin 5 mg + Metformin - adjusted mean change for Placebo + Metformin

4. Secondary Outcome Measure:

Measure Title	Change From Baseline in Mean Daily Glucose at Week 4
Measure Description	Adjusted mean change from baseline in daily glucose at Week 4. Mean daily glucose was calculated based on finger stick glucose measurements collected by the subjects at home in a 3-day period, prior to collection of the 24-hour blood samples at baseline and Week 4. Mean change from baseline was adjusted for baseline value.
Time Frame	Baseline, Week 4
Safety Issue?	No

Analysis Population Description

Randomized participants who took at least 1 dose of double-blind treatment. To be included in an analysis of change from baseline to Week 4 the subject must have had a baseline and a Week 4 measurement.

Reporting Groups

	Description
Saxagliptin 5 mg + Metformin	Saxagliptin tablets, 5 mg, taken orally once daily for 4 weeks, plus metformin XR.
Placebo + Metformin	Placebo tablets, taken orally once daily for 4 weeks, plus metformin XR.

Measured Values

	Saxagliptin 5 mg + Metformin	Placebo + Metformin
Number of Participants Analyzed	38	44
Change From Baseline in Mean Daily Glucose at Week 4 Mean (Standard Error) Unit of measure: mg/dL		
Baseline Mean	179.0 (5.76)	184.9 (7.14)
Week 4 Mean	167.5 (4.87)	191.8 (8.41)
Adjusted Change from Baseline	-11.7 (3.02)	7.0 (2.94)

Statistical Analysis 1 for Change From Baseline in Mean Daily Glucose at Week 4

Statistical Analysis Overview	Comparison Groups	Saxagliptin 5 mg + Metformin, Placebo + Metformin
	Comments	With 39 subjects per treatment group, there was a 93% power for the primary endpoint to detect a difference in 24-hour mean weighted glucose of 16 mg/dL between saxagliptin and placebo, assuming a standard deviation of 20 mg/dL. Assuming a dropout rate of 15%, a total of 92 subjects (46 subjects per treatment arm) needed to be randomized.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	<0.0001
	Comments	Between-group comparisons significant at alpha = 0.05, significance testing based on hierarchical testing. Primary and secondary endpoints are presented in order of testing.
	Method	ANCOVA
	Comments	ANCOVA Model: post - pre = pretreatment

Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	-18.7
	Confidence Interval	(2-Sided) 95% -27.1 to -10.3
	Parameter Dispersion	Type: Standard Error of the mean Value: 4.22
	Estimation Comments	Mean difference = adjusted mean change for saxagliptin 5 mg + Metformin - adjusted mean change for Placebo + Metformin

5. Secondary Outcome Measure:

Measure Title	Change From Baseline in 2-Day Average Fasting Plasma Glucose (FPG) at Week 4
Measure Description	Adjusted mean change from baseline in 2-day average of FPG at baseline and Week 4. Baseline value=the average of the values at Day -2 and Day 1. Week 4 measurement=average of Day 26 and Day 28 value during the double blind period. At pre-randomization and Day 28 the FPG value was the plasma glucose value collected 30 minutes prior to the morning meal during domicile visits. Mean change from baseline was adjusted for baseline value.
Time Frame	Baseline, Week 4
Safety Issue?	No

Analysis Population Description

Randomized participants who took at least 1 dose of double-blind treatment. To be included in an analysis of change from baseline to Week 4 the subject must have had a baseline and a Week 4 measurement.

Reporting Groups

	Description
Saxagliptin 5 mg + Metformin	Saxagliptin tablets, 5 mg, taken orally once daily for 4 weeks, plus metformin XR.
Placebo + Metformin	Placebo tablets, taken orally once daily for 4 weeks, plus metformin XR.

Measured Values

	Saxagliptin 5 mg + Metformin	Placebo + Metformin
Number of Participants Analyzed	46	47
Change From Baseline in 2-Day Average Fasting Plasma Glucose (FPG) at Week 4 Mean (Standard Error) Unit of measure: mg/dL		
Baseline Mean	152.2 (4.14)	158.9 (5.80)
Week 4 Last Observation Carried Forward Mean	141.9 (3.99)	162.9 (6.00)
Adjusted Mean Change from Baseline	-10.8 (2.84)	4.5 (2.81)

Statistical Analysis 1 for Change From Baseline in 2-Day Average Fasting Plasma Glucose (FPG) at Week 4

Statistical Analysis Overview	Comparison Groups	Saxagliptin 5 mg + Metformin, Placebo + Metformin
	Comments	With 39 subjects per treatment group, there was a 93% power for the primary endpoint to detect a difference in 24-hour mean weighted glucose of 16 mg/dL between saxagliptin and placebo, assuming a standard deviation of 20 mg/dL. Assuming a dropout rate of 15%, a total of 92 subjects (46 subjects per treatment arm) needed to be randomized.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0002
	Comments	Between-group comparisons significant at alpha = 0.05, significance testing based on hierarchical testing. Primary and secondary endpoints are presented in order of testing.
	Method	ANCOVA

	Comments	ANCOVA Model: post - pre = pretreatment

Method of Estimation	Estimation Parameter	Mean Difference (Final Values)
	Estimated Value	-15.3
	Confidence Interval	(2-Sided) 95% -23.3 to -7.4
	Parameter Dispersion	Type: Standard Error of the mean Value: 4.00
	Estimation Comments	Mean difference = adjusted mean change for saxagliptin 5 mg + Metformin - adjusted mean change for Placebo + Metformin

Reported Adverse Events

Time Frame	[Not specified]
Additional Description	[Not specified]

Reporting Groups

	Description
PLACEBO + MET	
SAXA 5MG + MET	

Serious Adverse Events

	PLACEBO + MET	SAXA 5MG + MET
	Affected/At Risk (%)	Affected/At Risk (%)
Total	0/47 (0%)	0/46 (0%)

Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 5%

	PLACEBO + MET	SAXA 5MG + MET
	Affected/At Risk (%)	Affected/At Risk (%)
Total	5/47 (10.64%)	1/46 (2.17%)
Gastrointestinal disorders		

	PLACEBO + MET	SAXA 5MG + MET
	Affected/At Risk (%)	Affected/At Risk (%)
NAUSEA [A] †	3/47 (6.38%)	0/46 (0%)
Nervous system disorders		
HEADACHE [A] †	3/47 (6.38%)	1/46 (2.17%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA 11.1

Limitations and Caveats

[Not specified]

More Information

Certain Agreements:

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

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

Bristol-Myers Squibb Co. agreements with investigators vary; constant is our right to embargo communications regarding trial results prior to public release for a period ≤60 days from submittal for review. We will not prohibit investigators from publishing, but will prohibit the disclosure of previously undisclosed confidential information other than study results, and request postponement of single-center publications until after disclosure of the clinical trial's primary publication.

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