ClinicalTrials.gov Protocol and Results Registration System (PRS) Receipt
Release Date: 05/16/2011

ClinicalTrials.gov ID: NCT00614939

Study Identification

Unique Protocol ID:	D1680C00007
Brief Title:	Treatment Effect of Saxagliptin Compared With Placebo in Patients With Type 2 Diabetes and Renal Impairment
Official Title:	A Short-term 12-Week, Multi-centre, Randomized, Parallel-group, Double-blind, Placebo-controlled Study to Evaluate the Treatment Effect of Saxagliptin Compared With Placebo in Adult Patients With Type 2 Diabetes and Renal Impairment (Moderate, Severe, and End-Stage) With an Additional 40-week, Randomized, Double-blind, Placebo-controlled Long-term Observational Period.
Secondary IDs:	EudraCT number 2007-004951-12

Study Status

Record Verification:	May 2011
Overall Status:	Completed
Study Start:	January 2008
Primary Completion:	June 2009 [Actual]
Study Completion:	March 2010 [Actual]

Sponsor/Collaborators

Sponsor:	AstraZeneca
Responsible Party:	
Collaborators:	Bristol-Myers Squibb

Oversight

FDA Regulated?:	No
IND/IDE Protocol?:	No
Review Board:	Approval Status: Approved Approval Number: 091107-99/335 Board Name: The Ethics Committee for Clinical Trials and Medicinal Products Board Affiliation: State Agency of Medicines Phone: 00371 67545106 Email: njp@osi.lv
Data Monitoring?:	Yes
Plan to Share Data?:	
Oversight Authorities:	Belarus: Ministry of Health Croatia: Ministry of Health and Social Care Czech Republic: State Institute for Drug Control Germany: Federal Institute for Drugs and Medical Devices Hungary: National Institute of Pharmacy Latvia: State Agency of Medicines Lithuania: State Medicine Control Agency - Ministry of Health Poland: Office for Registration of Medicinal Products, Medical Devices and Biocidal Products Romania: National Medicines Agency Russia: Ministry of Health of the Russian Federation Ukraine: State Pharmacological Center - Ministry of Health

Study Description

Brief Summary:	Saxagliptin is a new investigational medication being developed for treatment of type 2 diabetes. This study is designed to test the efficacy of once daily saxagliptin in renally impaired patients.
Detailed Description:	

Conditions

Conditions:	Type 2 Diabetes
Keywords:	DPP-4 inhibitors HbA1c incretins Renal Impairment

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 3
Intervention Model:	Parallel Assignment
Number of Arms:	2
Masking:	Double Blind (Subject, Caregiver, Investigator)
Allocation:	Randomized
Endpoint Classification:	Safety/Efficacy Study
Enrollment:	572 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: Saxa Saxagliptin	Drug: Saxagliptin 2.5 mg once daily oral dose Other Names: • Onglyza
No Intervention: Placebo Placebo to match	Drug: Placebo Placebo

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age:	18 Years
Maximum Age:	
Gender:	Both
Accepts Healthy Volunteers?:	No
Criteria:	Inclusion Criteria: • Diagnosed with type 2 diabetes

- Documented history of CrCl <50 ml/min within the 3 months prior to enrollment
- HbA1c ≥7.0% and ≤11.0%

Exclusion Criteria:

- Type 1 diabetes, history of diabetic ketoacidosis or hyposmolar non-ketonic coma
- Previous or current treatment with any DPP-IV inhibitor and/or GLP-1 mimetic.

Contacts/Locations

Study Officials: Peter Ohman, MD, PhD
Study Director
AstraZeneca

Deborah Price, MSc
Study Chair
AstraZeneca

Locations: Bulgaria
Research Site
Dimitrovgrad, Bulgaria

Research Site
Sofia, Bulgaria

Research Site
Veliko Tarnovo, Bulgaria

Czech Republic
Research Site
Moravsky Krumlov, Czech Republic

Germany
Research Site
Dusseldorf, Germany

Research Site
Mannheim, Germany

Hungary
Research Site
Zalaegerszeg, Hungary

Poland
Research Site

Warszawa, Poland

Research Site
Wroclaw, Poland

Research Site
Zabrze, Poland

Russian Federation
Research Site
Ryazan, Russian Federation

Research Site
Moscow, Russian Federation

Ukraine
Research Site
Mykolayiv, Ukraine

United States, Kansas
Research Site
Topeka, Kansas, United States

United States, Ohio
Research Site
Cincinnati, Ohio, United States

United States, West Virginia
Research Site
Charleston, West Virginia, United States

Belarus
Research Site
Brest, Belarus

Research Site
Gomel, Belarus

Research Site
Minsk, Belarus

Croatia
Research Site
Rijeka, Croatia, Croatia

Research Site

Karlovac, Croatia

Research Site
Osijek, Croatia

Research Site
Split, Croatia

Research Site
Zagreb, Croatia

Czech Republic
Research Site
Praha 10, Czech Republic

Research Site
Teplice, Czech Republic

Research Site
Usti Nad Labem, Czech Republic

Research Site
Znojmo, Czech Republic

Estonia
Research Site
Tallinn, Estonia

Germany
Research Site
Dieburg, Germany

Research Site
Hannover, Germany

Research Site
Heidelberg, Germany

Hungary
Research Site
Debrecen, Hungary

Research Site
Gyor, Hungary

Research Site

Kalocsa, Hungary

Research Site
Kecskemet, Hungary

Latvia
Research Site
Riga, Latvia

Lithuania
Research Site
Kaunas, Lithuania

Research Site
Klaipeda, Lithuania

Research Site
Panevezys, Lithuania

Research Site
Vilnius, Lithuania

Poland
Research Site
LODZ, 90-153, Poland

Research Site
Bialystok, Poland

Research Site
Ciechanow, Poland

Research Site
Golub Dobrzyn, Poland

Research Site
Grodzisk Mazowiecki, Poland

Research Site
Katowice, Poland

Research Site
Krakow, Poland

Research Site
Makow Mazowiecki, Poland

Research Site
Radom, Poland

Research Site
Szczecin, Poland

Romania
Research Site
Bacau, Bacau, Romania

Research Site
Brasov, Brasov, Romania

Research Site
Satu-mare, Satu Mare, Romania

Research Site
Bucharest, Romania

Research Site
Bucuresti, Romania

Research Site
Sf Gheorghe, Romania

Russian Federation
Research Site
Chelyabinsk, Russian Federation

Research Site
St.petersburg, Russian Federation

Research Site
Yaroslavl, Russian Federation

Ukraine
Research Site
Dnipropetrovsk, Ukraine

Research Site
Ivano-frankivsk, Ukraine

Research Site
Kharkiv, Ukraine

Research Site

Kyiv, Ukraine

Research Site
Sumy, Ukraine

Research Site
Ternopil, Ukraine

Research Site
Zaporizhzhya, Ukraine

United States, California
Research Site
Concord, California, United States

Research Site
Sacramento, California, United States

United States, Colorado
Research Site
Denver, Colorado, United States

United States, Maryland
Research Site
Baltimore, Maryland, United States

United States, Montana
Research Site
Great Falls, Montana, United States

United States, North Carolina
Research Site
Greenville, North Carolina, United States

Research Site
Morehead City, North Carolina, United States

United States, Texas
Research Site
Corpus Christi, Texas, United States

References

Citations:

Links:

Study Data/Documents:

Study Results

Participant Flow

Pre-Assignment Details	A total of 572 participants were enrolled in the study; 561 entered the Lead-in period and 170 patients were randomized and treated.

Reporting Groups

	Description
Placebo	Placebo
Saxa	Saxagliptin 2.5 mg once daily oral dose

Overall Study

	Placebo	Saxa
Started	85 [1]	85 [1]
Completed	50 [2]	42 [2]
Not Completed	35	43
Withdrawal by Subject	10	17
Study specific discontinuation criteris	13	16
Adverse Event	2	5
Incorrect enrollment	1	2
Death	4	3
Poor/non-compliance	4	0
Hospitalized due to kidney transplant	1	0

[1] Randomized and treated

[2] Completed 52 weeks of treatment

Baseline Characteristics

Reporting Groups

	Description
Placebo	Placebo
Saxa	Saxagliptin 2.5 mg once daily oral dose

Baseline Measures

	Placebo	Saxa	Total
Number of Participants	85	85	170
Age, Continuous [units: years] Mean (Standard Deviation)	66.2 (9.08)	66.8 (8.27)	66.5 (8.66)
Gender, Male/Female [units: Participants]			
Female	44	53	97
Male	41	32	73
Baseline Renal Impairment Category [units: Participants]			
Moderate	42	48	90
Severe	23	18	41
End-Stage	20	19	39
Baseline Diabetes Therapy [units: participants]			
Diabetes Therapy	84	83	167
Insulin	57	71	128
Oral blood glucose lowering drug	30	23	53

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Absolute Change From Baseline in Glycosylated Haemoglobin A1c (HbA1c) Level to Week 12 Last Observation Carried Forward (LOCF)
Measure Description	Adjusted* mean change from baseline in HbA1c achieved with saxagliptin 2.5 mg once daily versus placebo at Week 12 (Full Analysis Set). HbA1c is a continuous measure, the change from baseline for each participant is calculated at the Week 12 value minus the baseline value.
Time Frame	Baseline , Week 12 (LOCF)
Safety Issue?	No

Analysis Population Description

Randomized participants who took at least 1 dose of double-blind treatment. To be included in analysis: change from baseline to Week 12 (LOCF) for efficacy, subjects must have had a baseline and at least 1 post-baseline efficacy measurement.

Reporting Groups

	Description
Placebo	Placebo
Saxa	Saxagliptin 2.5 mg once daily oral dose

Measured Values

	Placebo	Saxa
Number of Participants Analyzed	83	81
Absolute Change From Baseline in Glycosylated Haemoglobin A1c (HbA1c) Level to Week 12 Last Observation Carried Forward (LOCF) [units: Percent] Mean (Standard Error)		
Baseline	8.09 (0.119)	8.45 (0.135)
Week 12	7.80 (0.137)	7.63 (0.132)
Adjusted Mean Change from Baseline	-0.44 (0.109)	-0.86 (0.112)

Statistical Analysis 1 for Absolute Change From Baseline in Glycosylated Haemoglobin A1c (HbA1c) Level to Week 12 Last Observation Carried Forward (LOCF)

Statistical Analysis Overview	Comparison Groups	Placebo, Saxa
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.007
	Comments	[Not specified]
	Method	ANCOVA
	Comments	*Adjusted for baseline HbA1c

Method of Estimation	Estimation Parameter	Mean Difference (Net)
	Estimated Value	-0.42
	Confidence Interval	(2-Sided) 95% -0.71 to -0.12
	Parameter Dispersion	Type: Standard Error of the mean Value: 0.151
	Estimation Comments	[Not specified]

2. Secondary Outcome Measure:

Measure Title	Absolute Change From Baseline in Fasting Plasma Glucose (FPG) to Week 12 (LOCF)- Moderate Renal Impairment Subgroup
Measure Description	Adjusted* mean change from baseline in fasting plasma glucose (FPG) achieved with saxagliptin 2.5 mg once daily versus placebo at Week 12 (Full Analysis Set) for the moderate renal impairment subgroup. FPG is a continuous measure, the change from baseline for each participant is calculated at the Week 12 value minus the baseline value.
Time Frame	Baseline, Week 12 (LOCF)
Safety Issue?	No

Analysis Population Description

Randomized participants who took at least 1 dose of double-blind treatment. To be included in analysis: change from baseline to Week 12 (LOCF) for efficacy, subjects must have had a baseline and at least 1 post-baseline efficacy measurement.

Reporting Groups

	Description
Placebo	Placebo
Saxa	Saxagliptin 2.5 mg once daily oral dose

Measured Values

	Placebo	Saxa
Number of Participants Analyzed	40	44
Absolute Change From Baseline in Fasting Plasma Glucose (FPG) to Week 12 (LOCF)- Moderate Renal Impairment Subgroup [units: mg/dL] Mean (Standard Error)		
Baseline	162.33 (8.933)	202.82 (9.858)
Week 12	174.50 (10.089)	173.91 (7.938)
Adjusted Mean Change from Baseline	-2.88 (9.073)	-15.22 (8.630)

Statistical Analysis 1 for Absolute Change From Baseline in Fasting Plasma Glucose (FPG) to Week 12 (LOCF)- Moderate Renal Impairment Subgroup

Statistical Analysis Overview	Comparison Groups	Placebo, Saxa
	Comments	Additional details about the analysis, such as null hypothesis and power calculation: Due to a statistically significant treatment-by-baseline renal impairment interaction, fasting plasma glucose results were analyzed separately for each baseline renal impairment category.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.339
	Comments	[Not specified]
	Method	ANCOVA
	Comments	*Adjusted for baseline FPG

Method of Estimation	Estimation Parameter	Mean Difference (Net)

	Estimated Value	-12.34
	Confidence Interval	(2-Sided) 95% -37.91 to 13.22
	Parameter Dispersion	Type: Standard Error of the mean Value: 12.847
	Estimation Comments	[Not specified]

3. Secondary Outcome Measure:

Measure Title	Absolute Change From Baseline in Fasting Plasma Glucose (FPG) to Week 12 (LOCF) - Severe Renal Impairment Subgroup
Measure Description	Adjusted* mean change from baseline in fasting plasma glucose (FPG) achieved with saxagliptin 2.5 mg once daily versus placebo at Week 12 (Full Analysis Set) for the severe renal impairment subgroup. FPG is a continuous measure, the change from baseline for each participant is calculated at the Week 12 value minus the baseline value.
Time Frame	Baseline, Week 12 (LOCF)
Safety Issue?	No

Analysis Population Description

Randomized participants who took at least 1 dose of double-blind treatment. To be included in analysis: change from baseline to Week 12 (LOCF) for efficacy, subjects must have had a baseline and at least 1 post-baseline efficacy measurement.

Reporting Groups

	Description
Placebo	Placebo
Saxa	Saxagliptin 2.5 mg once daily oral dose

Measured Values

	Placebo	Saxa
Number of Participants Analyzed	23	18
Absolute Change From Baseline in Fasting Plasma Glucose (FPG) to Week 12 (LOCF) - Severe Renal Impairment Subgroup [units: mg/dL] Mean (Standard Error)		
Baseline	173.48 (11.630)	165.50 (19.909)
Week 12	141.52 (14.276)	133.83 (11.371)

	Placebo	Saxa
Adjusted mean change	-29.91 (11.212)	-34.28 (12.677)

Statistical Analysis 1 for Absolute Change From Baseline in Fasting Plasma Glucose (FPG) to Week 12 (LOCF) - Severe Renal Impairment Subgroup

Statistical Analysis Overview	Comparison Groups	Placebo, Saxa
	Comments	Additional details about the analysis, such as null hypothesis and power calculation: Due to a statistically significant treatment-by-baseline renal impairment interaction, fasting plasma glucose results were analyzed separately for each baseline renal impairment category.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.798
	Comments	[Not specified]
	Method	ANCOVA
	Comments	*Adjusted for baseline FPG

Method of Estimation	Estimation Parameter	Mean Difference (Net)
	Estimated Value	-4.36
	Confidence Interval	(2-Sided) 95% -38.65 to 29.93
	Parameter Dispersion	Type: Standard Error of the mean Value: 16.938
	Estimation Comments	[Not specified]

4. Secondary Outcome Measure:

Measure Title	Absolute Change From Baseline in Fasting Plasma Glucose (FPG) to Week 12 (LOCF) - End-Stage Renal Impairment Subgroup
Measure Description	Adjusted* mean change from baseline in fasting plasma glucose (FPG) achieved with saxagliptin 2.5 mg once daily versus placebo at Week 12 (Full Analysis Set) for the end-stage renal impairment subgroup. FPG is a continuous measure, the change from baseline for each participant is calculated at the Week 12 value minus the baseline value.

Time Frame	Baseline, Week 12 (LOCF)
Safety Issue?	No

Analysis Population Description

Randomized participants who took at least 1 dose of double-blind treatment. To be included in analysis: change from baseline to Week 12 (LOCF) for efficacy, subjects must have had a baseline and at least 1 post-baseline efficacy measurement.

Reporting Groups

	Description
Placebo	Placebo
Saxa	Saxagliptin 2.5 mg once daily oral dose

Measured Values

	Placebo	Saxa
Number of Participants Analyzed	18	15
Absolute Change From Baseline in Fasting Plasma Glucose (FPG) to Week 12 (LOCF) - End-Stage Renal Impairment Subgroup [units: mg/dL] Mean (Standard Error)		
Baseline	170.39 (14.518)	177.07 (10.638)
Week 12	161.11 (12.624)	207.60 (30.515)
Adjusted mean change	-11.18 (20.752)	32.82 (22.737)

Statistical Analysis 1 for Absolute Change From Baseline in Fasting Plasma Glucose (FPG) to Week 12 (LOCF) - End-Stage Renal Impairment Subgroup

Statistical Analysis Overview	Comparison Groups	Placebo, Saxa
	Comments	Additional details about the analysis, such as null hypothesis and power calculation: Due to a statistically significant treatment-by-baseline renal impairment interaction, fasting plasma glucose results were analyzed separately for each baseline renal impairment category.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.164
	Comments	[Not specified]
	Method	ANCOVA
	Comments	*Adjusted for baseline FPG

Method of Estimation	Estimation Parameter	Mean Difference (Net)
	Estimated Value	44.01
	Confidence Interval	(2-Sided) 95% -18.93 to 106.94
	Parameter Dispersion	Type: Standard Error of the mean Value: 30.815
	Estimation Comments	[Not specified]

5. Secondary Outcome Measure:

Measure Title	Absolute Change From Baseline in Fasting Plasma Glucose (FPG) to Week 12 (LOCF) - Moderate Renal Impairment Subgroup
Measure Description	Adjusted* mean change from baseline in fasting plasma glucose (FPG) achieved with saxagliptin 2.5 mg once daily versus placebo at Week 12 (Full Analysis Set) for the moderate renal impairment subgroup. FPG is a continuous measure, the change from baseline for each participant is calculated at the Week 12 value minus the baseline value.
Time Frame	Baseline, Week 12 (LOCF)
Safety Issue?	No

Analysis Population Description

Randomized participants who took at least 1 dose of double-blind treatment. To be included in analysis: change from baseline to Week 12 (LOCF) for efficacy, subjects must have had a baseline and at least 1 post-baseline efficacy measurement.

Reporting Groups

	Description
Placebo	Placebo
Saxa	Saxagliptin 2.5 mg once daily oral dose

Measured Values

	Placebo	Saxa
Number of Participants Analyzed	40	44

	Placebo	Saxa
Absolute Change From Baseline in Fasting Plasma Glucose (FPG) to Week 12 (LOCF) - Moderate Renal Impairment Subgroup [units: mmol/L] Mean (Standard Error)		
Baseline	9.01 (0.495)	11.25 (0.548)
Week 12	9.68 (0.560)	9.65 (0.441)
Absolute mean change	-0.16 (0.504)	-0.84 (0.479)

Statistical Analysis 1 for Absolute Change From Baseline in Fasting Plasma Glucose (FPG) to Week 12 (LOCF) - Moderate Renal Impairment Subgroup

Statistical Analysis Overview	Comparison Groups	Placebo, Saxa
	Comments	Additional details about the analysis, such as null hypothesis and power calculation: Due to a statistically significant treatment-by-baseline renal impairment interaction, fasting plasma glucose results were analyzed separately for each baseline renal impairment category.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	
	Comments	[Not specified]
	Method	Other [Footnote]
	Comments	*Adjusted for baseline FPG

Method of Estimation	Estimation Parameter	Mean Difference (Net)
	Estimated Value	-0.68
	Confidence Interval	(2-Sided) 95% -2.10 to 0.74
	Parameter Dispersion	Type: Standard Error of the mean Value: 0.713
	Estimation Comments	[Not specified]

6. Secondary Outcome Measure:

Measure Title	Absolute Change From Baseline in Fasting Plasma Glucose (FPG) to Week 12 (LOCF) - Severe Renal Impairment Subgroup
Measure Description	Adjusted* mean change from baseline in fasting plasma glucose (FPG) achieved with saxagliptin 2.5 mg once daily versus placebo at Week 12 (Full Analysis Set) for the severe renal impairment subgroup. FPG is a continuous measure, the change from baseline for each participant is calculated at the Week 12 value minus the baseline value.
Time Frame	Baseline, Week 12 (LOCF)
Safety Issue?	No

Analysis Population Description

Randomized participants who took at least 1 dose of double-blind treatment. To be included in analysis: change from baseline to Week 12 (LOCF) for efficacy, subjects must have had a baseline and at least 1 post-baseline efficacy measurement.

Reporting Groups

	Description
Placebo	Placebo
Saxa	Saxagliptin 2.5 mg once daily oral dose

Measured Values

	Placebo	Saxa
Number of Participants Analyzed	23	18
Absolute Change From Baseline in Fasting Plasma Glucose (FPG) to Week 12 (LOCF) - Severe Renal Impairment Subgroup [units: mmol/L] Mean (Standard Error)		
Baseline	9.63 (0.646)	9.17 (1.105)
Week 12	7.86 (0.793)	7.43 (0.632)
Adjusted mean change	-1.66 (0.623)	-1.89 (0.704)

Statistical Analysis 1 for Absolute Change From Baseline in Fasting Plasma Glucose (FPG) to Week 12 (LOCF) - Severe Renal Impairment Subgroup

Statistical Analysis Overview	Comparison Groups	Placebo, Saxa

	Comments	Additional details about the analysis, such as null hypothesis and power calculation: Due to a statistically significant treatment-by-baseline renal impairment interaction, fasting plasma glucose results were analyzed separately for each baseline renal impairment category.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	
	Comments	[Not specified]
	Method	Other [Footnote]
	Comments	*Adjusted for baseline FPG

Method of Estimation	Estimation Parameter	Mean Difference (Net)
	Estimated Value	-0.24
	Confidence Interval	(2-Sided) 95% -2.14 to 1.67
	Parameter Dispersion	Type: Standard Error of the mean Value: 0.941
	Estimation Comments	[Not specified]

7. Secondary Outcome Measure:

Measure Title	Absolute Change From Baseline in Fasting Plasma Glucose (FPG) to Week 12 (LOCF) - End-Stage Renal Impairment Subgroup
Measure Description	Adjusted* mean change from baseline in fasting plasma glucose (FPG) achieved with saxagliptin 2.5 mg once daily versus placebo at Week 12 (Full Analysis Set) for the end-stage renal impairment subgroup. FPG is a continuous measure, the change from baseline for each participant is calculated at the Week 12 value minus the baseline value.
Time Frame	Baseline, Week 12 (LOCF)
Safety Issue?	No

Analysis Population Description

Randomized participants who took at least 1 dose of double-blind treatment. To be included in analysis: change from baseline to Week 12 (LOCF) for efficacy, subjects must have had a baseline and at least 1 post-baseline efficacy measurement.

Reporting Groups

	Description
Placebo	Placebo
Saxa	Saxagliptin 2.5 mg once daily oral dose

Measured Values

	Placebo	Saxa
Number of Participants Analyzed	18	15
Absolute Change From Baseline in Fasting Plasma Glucose (FPG) to Week 12 (LOCF) - End-Stage Renal Impairment Subgroup [units: mmol/L] Mean (Standard Error)		
Baseline	9.46 (0.807)	9.83 (0.591)
Week 12	8.94 (0.700)	11.52 (1.692)
Adjusted mean change	-0.62 (1.151)	1.81 (1.261)

Statistical Analysis 1 for Absolute Change From Baseline in Fasting Plasma Glucose (FPG) to Week 12 (LOCF) - End-Stage Renal Impairment Subgroup

Statistical Analysis Overview	Comparison Groups	Placebo, Saxa
	Comments	Additional details about the analysis, such as null hypothesis and power calculation: Due to a statistically significant treatment-by-baseline renal impairment interaction, fasting plasma glucose results were analyzed separately for each baseline renal impairment category.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	
	Comments	[Not specified]
	Method	Other [Footnote]
	Comments	*Adjusted for baseline FPG

Method of Estimation	Estimation Parameter	Mean Difference (Net)

	Estimated Value	2.44
	Confidence Interval	(2-Sided) 95% -1.05 to 5.93
	Parameter Dispersion	Type: Standard Error of the mean Value: 1.709
	Estimation Comments	[Not specified]

8. Secondary Outcome Measure:

Measure Title	Absolute Change From Baseline in Glycosylated Haemoglobin A1c (HbA1c) Level to Week 52
Measure Description	Adjusted* mean change from baseline in HbA1c achieved with saxagliptin 2.5 mg once daily versus placebo at Week 52 (Full Analysis Set). HbA1c is a continuous measure, the change from baseline for each participant is calculated at the Week 52 value minus the baseline value.
Time Frame	Baseline , Week 52
Safety Issue?	No

Analysis Population Description

Randomized participants who took at least 1 dose of double-blind treatment. To be included in analysis: change from baseline to Week 52 for efficacy, subjects must have had a baseline and at least 1 post-baseline efficacy measurement. Data were excluded after changes in oral blood glucose lowering drug or insulin.

Reporting Groups

	Description
Placebo	Placebo
Saxa	Saxagliptin 2.5 mg once daily oral dose

Measured Values

	Placebo	Saxa
Number of Participants Analyzed	82	78
Absolute Change From Baseline in Glycosylated Haemoglobin A1c (HbA1c) Level to Week 52 [units: Percent] Mean (Standard Error)		
Baseline	8.10 (0.120)	8.44 (0.134)
Week 52	7.93 (0.173)	7.41 (0.138)
Adjusted mean change	-0.53 (0.154)	-1.35 (0.174)

Statistical Analysis 1 for Absolute Change From Baseline in Glycosylated Haemoglobin A1c (HbA1c) Level to Week 52

Statistical Analysis Overview	Comparison Groups	Placebo, Saxa
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	
	Comments	[Not specified]
	Method	Other [Repeated Measures]
	Comments	Number of subjects with observed values at Week 52 was n=26 for saxagliptin and n=34 for placebo *Adjusted for baseline HbA1c

Method of Estimation	Estimation Parameter	Mean Difference (Net)
	Estimated Value	-0.82
	Confidence Interval	(2-Sided) 95% -1.27 to -0.37
	Parameter Dispersion	Type: Standard Error of the mean Value: 0.228
	Estimation Comments	[Not specified]

9. Secondary Outcome Measure:

Measure Title	Absolute Change From Baseline in Fasting Plasma Glucose (FPG) to Week 52 - Moderate Renal Impairment Subgroup
Measure Description	Adjusted* mean change from baseline in fasting plasma glucose (FPG) achieved with saxagliptin 2.5 mg once daily versus placebo at Week 52 (Full Analysis Set) for the moderate renal impairment subgroup. FPG is a continuous measure, the change from baseline for each participant is calculated at the Week 52 value minus the baseline value.
Time Frame	Baseline, Week 52
Safety Issue?	No

Analysis Population Description

Randomized participants who took at least 1 dose of double-blind treatment. To be included in analysis: change from baseline to Week 52 for efficacy, subjects must have had a baseline and at least 1 post-baseline efficacy measurement. Data were excluded after changes in oral blood glucose lowering drug or insulin.

Reporting Groups

	Description
Placebo	Placebo
Saxa	Saxagliptin 2.5 mg once daily oral dose

Measured Values

	Placebo	Saxa
Number of Participants Analyzed	40	44
Absolute Change From Baseline in Fasting Plasma Glucose (FPG) to Week 52 - Moderate Renal Impairment Subgroup [units: mg/dL] Mean (Standard Error)		
Baseline	162.33 (8.933)	202.82 (9.858)
Week 52	174.83 (11.295)	177.43 (7.637)
Adjusted mean change	3.02 (13.277)	-14.96 (12.873)

Statistical Analysis 1 for Absolute Change From Baseline in Fasting Plasma Glucose (FPG) to Week 52 - Moderate Renal Impairment Subgroup

Statistical Analysis Overview	Comparison Groups	Placebo, Saxa
	Comments	Additional details about the analysis, such as null hypothesis and power calculation: Due to a statistically significant treatment-by-baseline renal impairment interaction, fasting plasma glucose results were analyzed separately for each baseline renal impairment category.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	
	Comments	[Not specified]

	Method	Other [Repeated Measures]
	Comments	Number of subjects with observed values at Week 52 was n=17 for saxagliptin and n=16 for placebo *Adjusted for baseline FPG

Method of Estimation	Estimation Parameter	Mean Difference (Net)
	Estimated Value	-17.98
	Confidence Interval	(2-Sided) 95% -54.28 to 18.33
	Parameter Dispersion	Type: Standard Error of the mean Value: 18.475
	Estimation Comments	[Not specified]

10. Secondary Outcome Measure:

Measure Title	Absolute Change From Baseline in Fasting Plasma Glucose (FPG) to Week 52 - Severe Renal Impairment Subgroup
Measure Description	Adjusted* mean change from baseline in fasting plasma glucose (FPG) achieved with saxagliptin 2.5 mg once daily versus placebo at Week 52 (Full Analysis Set) for the severe renal impairment subgroup. FPG is a continuous measure, the change from baseline for each participant is calculated at the Week 52 value minus the baseline value.
Time Frame	Baseline, Week 52
Safety Issue?	No

Analysis Population Description

Randomized participants who took at least 1 dose of double-blind treatment. To be included in analysis: change from baseline to Week 52 for efficacy, subjects must have had a baseline and at least 1 post-baseline efficacy measurement. Data were excluded after changes in oral blood glucose lowering drug or insulin.

Reporting Groups

	Description
Placebo	Placebo
Saxa	Saxagliptin 2.5 mg once daily oral dose

Measured Values

	Placebo	Saxa
Number of Participants Analyzed	23	18

	Placebo	Saxa
Absolute Change From Baseline in Fasting Plasma Glucose (FPG) to Week 52 - Severe Renal Impairment Subgroup [units: mg/dL] Mean (Standard Error)		
Baseline	173.48 (11.630)	165.50 (19.909)
Week 52	151.78 (9.896)	139.06 (12.408)
Adjusted mean change	-24.59 (14.510)	-40.32 (20.789)

Statistical Analysis 1 for Absolute Change From Baseline in Fasting Plasma Glucose (FPG) to Week 52 - Severe Renal Impairment Subgroup

Statistical Analysis Overview	Comparison Groups	Placebo, Saxa
	Comments	Additional details about the analysis, such as null hypothesis and power calculation: Due to a statistically significant treatment-by-baseline renal impairment interaction, fasting plasma glucose results were analyzed separately for each baseline renal impairment category.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	
	Comments	[Not specified]
	Method	Other [Repeated Measures]
	Comments	Number of subjects with observed values at Week 52 was n=5 for saxagliptin and n=11 for placebo. *Adjusted for baseline FPG

Method of Estimation	Estimation Parameter	Mean Difference (Net)
	Estimated Value	-15.73
	Confidence Interval	(2-Sided) 95% -65.77 to 34.30
	Parameter Dispersion	Type: Standard Error of the mean Value: 25.326

	Estimation Comments	[Not specified]

11. Secondary Outcome Measure:

Measure Title	Absolute Change From Baseline in Fasting Plasma Glucose (FPG) to Week 52 - End-Stage Renal Impairment Subgroup
Measure Description	Adjusted* mean change from baseline in fasting plasma glucose (FPG) achieved with saxagliptin 2.5 mg once daily versus placebo at Week 52 (Full Analysis Set) for the end-stage renal impairment subgroup. FPG is a continuous measure, the change from baseline for each participant is calculated at the Week 52 value minus the baseline value.
Time Frame	Baseline, Week 52
Safety Issue?	No

Analysis Population Description

Randomized participants who took at least 1 dose of double-blind treatment. To be included in analysis: change from baseline to Week 52 for efficacy, subjects must have had a baseline and at least 1 post-baseline efficacy measurement. Data were excluded after changes in oral blood glucose lowering drug or insulin.

Reporting Groups

	Description
Placebo	Placebo
Saxa	Saxagliptin 2.5 mg once daily oral dose

Measured Values

	Placebo	Saxa
Number of Participants Analyzed	18	15
Absolute Change From Baseline in Fasting Plasma Glucose (FPG) to Week 52 - End-Stage Renal Impairment Subgroup [units: mg/dL] Mean (Standard Error)		
Baseline	170.39 (14.518)	177.07 (10.638)
Week 52	161.94 (13.097)	214.27 (31.740)
Adjusted mean change	-2.18 (29.226)	-40.28 (45.470)

Statistical Analysis 1 for Absolute Change From Baseline in Fasting Plasma Glucose (FPG) to Week 52 - End-Stage Renal Impairment Subgroup

Statistical Analysis Overview	Comparison Groups	Placebo, Saxa
	Comments	Additional details about the analysis, such as null hypothesis and power calculation: Due to a statistically significant treatment-by-baseline renal impairment interaction, fasting plasma glucose results were analyzed separately for each baseline renal impairment category.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	
	Comments	[Not specified]
	Method	Other [Repeated Measures]
	Comments	Number of subjects with observed values at Week 52 was n=2 for saxagliptin and n=5 for placebo. *Adjusted for baseline FPG

Method of Estimation	Estimation Parameter	Mean Difference (Net)
	Estimated Value	-38.09
	Confidence Interval	(2-Sided) 95% -144.44 to 68.26
	Parameter Dispersion	Type: Standard Error of the mean Value: 53.822
	Estimation Comments	[Not specified]

12. Secondary Outcome Measure:

Measure Title	Absolute Change From Baseline in Fasting Plasma Glucose (FPG) to Week 52 - Moderate Renal Impairment Subgroup
Measure Description	Adjusted* mean change from baseline in fasting plasma glucose (FPG) achieved with saxagliptin 2.5 mg once daily versus placebo at Week 52 (Full Analysis Set) for the moderate renal impairment subgroup. FPG is a continuous measure, the change from baseline for each participant is calculated at the Week 52 value minus the baseline value
Time Frame	Baseline, Week 52
Safety Issue?	No

Analysis Population Description

Randomized participants who took at least 1 dose of double-blind treatment. To be included in analysis: change from baseline to Week 52 for efficacy, subjects must have had a baseline and at least 1 post-baseline efficacy measurement. Data were excluded after changes in oral blood glucose lowering drug or insulin.

Reporting Groups

	Description
Placebo	Placebo
Saxa	Saxagliptin 2.5 mg once daily oral dose

Measured Values

	Placebo	Saxa
Number of Participants Analyzed	40	44
Absolute Change From Baseline in Fasting Plasma Glucose (FPG) to Week 52 - Moderate Renal Impairment Subgroup [units: mmol/L] Mean (Standard Error)		
Baseline	9.01 (0.495)	11.25 (0.548)
Week 52	9.70 (0.627)	9.85 (0.424)
Adjusted mean change	0.15 (0.738)	-0.82 (0.715)

Statistical Analysis 1 for Absolute Change From Baseline in Fasting Plasma Glucose (FPG) to Week 52 - Moderate Renal Impairment Subgroup

Statistical Analysis Overview	Comparison Groups	Placebo, Saxa
	Comments	Additional details about the analysis, such as null hypothesis and power calculation: Due to a statistically significant treatment-by-baseline renal impairment interaction, fasting plasma glucose results were analyzed separately for each baseline renal impairment category.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	
	Comments	[Not specified]

	Method	Other [Repeated Measures]
	Comments	Number of subjects with observed values at Week 52 was n=17 for saxagliptin and n=16 for placebo. *Adjusted for baseline FPG

Method of Estimation	Estimation Parameter	Mean Difference (Net)
	Estimated Value	-0.97
	Confidence Interval	(2-Sided) 95% -2.99 to 1.04
	Parameter Dispersion	Type: Standard Error of the mean Value: 1.027
	Estimation Comments	[Not specified]

13. Secondary Outcome Measure:

Measure Title	Absolute Change From Baseline in Fasting Plasma Glucose (FPG) to Week 52 - Severe Renal Impairment Subgroup
Measure Description	Adjusted* mean change from baseline in fasting plasma glucose (FPG) achieved with saxagliptin 2.5 mg once daily versus placebo at Week 52 (Full Analysis Set) for the severe renal impairment subgroup. FPG is a continuous measure, the change from baseline for each participant is calculated at the Week 52 value minus the baseline value.
Time Frame	Baseline, Week 52
Safety Issue?	No

Analysis Population Description

Randomized participants who took at least 1 dose of double-blind treatment. To be included in analysis: change from baseline to Week 52 for efficacy, subjects must have had a baseline and at least 1 post-baseline efficacy measurement. Data were excluded after changes in oral blood glucose lowering drug or insulin.

Reporting Groups

	Description
Placebo	Placebo
Saxa	Saxagliptin 2.5 mg once daily oral dose

Measured Values

	Placebo	Saxa
Number of Participants Analyzed	23	18

	Placebo	Saxa
Absolute Change From Baseline in Fasting Plasma Glucose (FPG) to Week 52 - Severe Renal Impairment Subgroup [units: mmol/L] Mean (Standard Error)		
Baseline	9.63 (0.646)	9.17 (1.105)
Week 52	8.42 (0.551)	7.71 (0.688)
Adjusted mean change	-1.37 (0.805)	-2.25 (1.154)

Statistical Analysis 1 for Absolute Change From Baseline in Fasting Plasma Glucose (FPG) to Week 52 - Severe Renal Impairment Subgroup

Statistical Analysis Overview	Comparison Groups	Placebo, Saxa
	Comments	Additional details about the analysis, such as null hypothesis and power calculation: Due to a statistically significant treatment-by-baseline renal impairment interaction, fasting plasma glucose results were analyzed separately for each baseline renal impairment category.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	
	Comments	[Not specified]
	Method	Other [Repeated Measures]
	Comments	Number of subjects with observed values at Week 52 was n=5 for saxagliptin and n=11 for placebo. *Adjusted for baseline FPG

Method of Estimation	Estimation Parameter	Mean Difference (Net)
	Estimated Value	-0.89
	Confidence Interval	(2-Sided) 95% -3.66 to 1.89
	Parameter Dispersion	Type: Standard Error of the mean Value: 1.405

	Estimation Comments	[Not specified]

14. Secondary Outcome Measure:

Measure Title	Absolute Change From Baseline in Fasting Plasma Glucose (FPG) to Week 52 - End-Stage Renal Impairment Subgroup
Measure Description	Adjusted* mean change from baseline in fasting plasma glucose (FPG) achieved with saxagliptin 2.5 mg once daily versus placebo at Week 52 (Full Analysis Set) for the end-stage renal impairment subgroup. FPG is a continuous measure, the change from baseline for each participant is calculated at the Week 52 value minus the baseline value.
Time Frame	Baseline, Week 52
Safety Issue?	No

Analysis Population Description

Randomized participants who took at least 1 dose of double-blind treatment. To be included in analysis: change from baseline to Week 52 for efficacy, subjects must have had a baseline and at least 1 post-baseline efficacy measurement. Data were excluded after changes in oral blood glucose lowering drug or insulin.

Reporting Groups

	Description
Placebo	Placebo
Saxa	Saxagliptin 2.5 mg once daily oral dose

Measured Values

	Placebo	Saxa
Number of Participants Analyzed	18	15
Absolute Change From Baseline in Fasting Plasma Glucose (FPG) to Week 52 - End-Stage Renal Impairment Subgroup [units: mmol/L] Mean (Standard Error)		
Baseline	9.46 (0.807)	9.83 (0.591)
Week 52	8.99 (0.728)	11.89 (1.760)
Adjusted mean change	-0.11 (1.621)	-2.25 (2.522)

Statistical Analysis 1 for Absolute Change From Baseline in Fasting Plasma Glucose (FPG) to Week 52 - End-Stage Renal Impairment Subgroup

Statistical Analysis Overview	Comparison Groups	Placebo, Saxa
	Comments	Additional details about the analysis, such as null hypothesis and power calculation: Due to a statistically significant treatment-by-baseline renal impairment interaction, fasting plasma glucose results were analyzed separately for each baseline renal impairment category.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	
	Comments	[Not specified]
	Method	Other [Repeated Measures]
	Comments	Number of subjects with observed values at Week 52 was n=2 for saxagliptin and n=5 for placebo. *Adjusted for baseline FPG

Method of Estimation	Estimation Parameter	Mean Difference (Net)
	Estimated Value	-2.14
	Confidence Interval	(2-Sided) 95% -8.04 to 3.76
	Parameter Dispersion	Type: Standard Error of the mean Value: 2.985
	Estimation Comments	[Not specified]

Reported Adverse Events

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

Reporting Groups

	Description
Placebo	Placebo
Saxa	Saxagliptin 2.5 mg once daily oral dose

Serious Adverse Events

	Placebo	Saxa
	Affected/At Risk (%)	Affected/At Risk (%)
Total	24/85 (28.24%)	23/85 (27.06%)
Cardiac disorders		
Acute Myocardial Infarction [A] †	0/85 (0%)	1/85 (1.18%)
Atrial Fibrillation [A] †	1/85 (1.18%)	0/85 (0%)
Bifascicular Block [A] †	1/85 (1.18%)	0/85 (0%)
Cardiac Arrest [A] †	0/85 (0%)	1/85 (1.18%)
Cardiac Failure [A] †	2/85 (2.35%)	0/85 (0%)
Cardiac Failure Congestive [A] †	0/85 (0%)	1/85 (1.18%)
Myocardial Infarction [A] †	1/85 (1.18%)	2/85 (2.35%)
Eye disorders		
Cataract [A] †	0/85 (0%)	1/85 (1.18%)
Iridocyclitis [A] †	0/85 (0%)	1/85 (1.18%)
Pseudoexfoliation Of Lens Capsule [A] †	0/85 (0%)	1/85 (1.18%)
Gastrointestinal disorders		
Abdominal Pain Upper [A] †	0/85 (0%)	1/85 (1.18%)
Diarrhoea [A] †	0/85 (0%)	1/85 (1.18%)
Gastrointestinal Haemorrhage [A] †	0/85 (0%)	1/85 (1.18%)
Oedema [A] †	1/85 (1.18%)	0/85 (0%)

	Placebo	Saxa
	Affected/At Risk (%)	Affected/At Risk (%)
Pancreatitis [A] †	1/85 (1.18%)	0/85 (0%)
General disorders		
Oedema Peripheral [A] †	0/85 (0%)	1/85 (1.18%)
Sudden Death [A] †	2/85 (2.35%)	1/85 (1.18%)
Infections and infestations		
Cellulitis [A] †	0/85 (0%)	1/85 (1.18%)
Cystitis [A] †	0/85 (0%)	1/85 (1.18%)
Gangrene [A] †	1/85 (1.18%)	1/85 (1.18%)
Infected Skin Ulcer [A] †	1/85 (1.18%)	0/85 (0%)
Lobar Pneumonia [A] †	1/85 (1.18%)	0/85 (0%)
Osteomyelitis [A] †	1/85 (1.18%)	0/85 (0%)
Pneumonia [A] †	0/85 (0%)	2/85 (2.35%)
Pyelonephritis [A] †	0/85 (0%)	1/85 (1.18%)
Pyelonephritis Acute [A] †	1/85 (1.18%)	1/85 (1.18%)
Sepsis [A] †	1/85 (1.18%)	0/85 (0%)
Urinary Tract Infection [A] †	0/85 (0%)	1/85 (1.18%)
Urosepsis [A] †	1/85 (1.18%)	0/85 (0%)
Injury, poisoning and procedural complications		
Arteriovenous Fistula Operation [A] †	1/85 (1.18%)	0/85 (0%)
Arteriovenous Fistula Thrombosis [A] †	1/85 (1.18%)	0/85 (0%)
Upper Limb Fracture [A] †	1/85 (1.18%)	0/85 (0%)
Wound [A] †	1/85 (1.18%)	0/85 (0%)
Investigations		

	Placebo	Saxa
	Affected/At Risk (%)	Affected/At Risk (%)
Alanine Aminotransferase Increased [A] †	0/85 (0%)	1/85 (1.18%)
Aspartate Aminotransferase Increased [A] †	0/85 (0%)	1/85 (1.18%)
Blood Glucose Increased [A] †	0/85 (0%)	1/85 (1.18%)
Metabolism and nutrition disorders		
Diabetes Mellitus [A] †	1/85 (1.18%)	0/85 (0%)
Diabetes Mellitus Inadequate Control [A] †	1/85 (1.18%)	1/85 (1.18%)
Hyperglycaemia [A] †	1/85 (1.18%)	0/85 (0%)
Hypoglycaemia [A] †	2/85 (2.35%)	0/85 (0%)
Musculoskeletal and connective tissue disorders		
Osteochondrosis [A] †	1/85 (1.18%)	0/85 (0%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Malignant Fibrous Histiocytoma [A] †	0/85 (0%)	1/85 (1.18%)
Nervous system disorders		
Cauda Equina Syndrome [A] †	0/85 (0%)	1/85 (1.18%)
Cerebral Hypoperfusion [A] †	1/85 (1.18%)	0/85 (0%)
Cerebrovascular Accident [A] †	1/85 (1.18%)	1/85 (1.18%)
Dizziness [A] †	0/85 (0%)	1/85 (1.18%)
Renal and urinary disorders		
Calculus Ureteric [A] †	0/85 (0%)	1/85 (1.18%)
Renal Failure Chronic [A] †	1/85 (1.18%)	0/85 (0%)
Renal Impairment [A] †	1/85 (1.18%)	1/85 (1.18%)
Respiratory, thoracic and mediastinal disorders		
Dyspnoea [A] †	0/85 (0%)	1/85 (1.18%)

	Placebo	Saxa
	Affected/At Risk (%)	Affected/At Risk (%)
Interstitial Lung Disease [A] †	0/85 (0%)	1/85 (1.18%)
Orthopnoea [A] †	0/85 (0%)	1/85 (1.18%)
Skin and subcutaneous tissue disorders		
Skin Disorder [A] †	1/85 (1.18%)	0/85 (0%)
Skin Ulcer [A] †	0/85 (0%)	1/85 (1.18%)
Vascular disorders		
Arteriosclerosis [A] †	1/85 (1.18%)	0/85 (0%)
Arteriovenous Fistula [A] †	0/85 (0%)	1/85 (1.18%)
Femoral Artery Occlusion [A] †	1/85 (1.18%)	0/85 (0%)
Hypertension [A] †	0/85 (0%)	1/85 (1.18%)
Hypertensive crisis [A] †	1/85 (1.18%)	0/85 (0%)
Orthostatic Hypotension [A] †	0/85 (0%)	1/85 (1.18%)
Peripheral Arterial Occlusive Disease [A] †	1/85 (1.18%)	0/85 (0%)
Peripheral Ischaemia [A] †	1/85 (1.18%)	0/85 (0%)
Poor Peripheral Circulation [A] †	0/85 (0%)	1/85 (1.18%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA 12.1

Other Adverse Events

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

	Placebo	Saxa
	Affected/At Risk (%)	Affected/At Risk (%)
Total	36/85 (42.35%)	38/85 (44.71%)
Blood and lymphatic system disorders		
Anaemia [A] †	7/85 (8.24%)	5/85 (5.88%)

	Placebo	Saxa
	Affected/At Risk (%)	Affected/At Risk (%)
General disorders		
Oedema Peripheral [A] †	6/85 (7.06%)	2/85 (2.35%)
Infections and infestations		
Urinary Tract Infection [A] †	3/85 (3.53%)	5/85 (5.88%)
Metabolism and nutrition disorders		
Hypoglycaemia [A] †	25/85 (29.41%)	24/85 (28.24%)
Vascular disorders		
Hypertension [A] †	5/85 (5.88%)	5/85 (5.88%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA 12.1

Limitations and Caveats

[Not specified]

More Information

Certain Agreements:

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

There is NOT 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.

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