ClinicalTrials.gov Protocol and Results Registration System (PRS) Receipt
Release Date: 08/30/2011

ClinicalTrials.gov ID: NCT00296374

Study Identification

Unique Protocol ID:	D3569C00007
Brief Title:	Prospective Evaluation of Proteinuria and Renal Function in Diabetic Patients With Progressive Renal Disease (PLANET 1)
Official Title:	Randomised, Double-blind, 52-wk, Parallel-grp, Multicentre, PIIb Study to Evaluate Effects of Rosuvastatin 10mg, Rosuvastatin 40mg and Atorvastatin 80mg on Urinary Protein Excretion in Hypercholesterolaemic Diabetic Patients With Moderate Proteinuria
Secondary IDs:	PLANET 1

Study Status

Record Verification:	August 2011
Overall Status:	Completed
Study Start:	February 2006
Primary Completion:	March 2009 [Actual]
Study Completion:	March 2009 [Actual]

Sponsor/Collaborators

Sponsor:	AstraZeneca
Responsible Party:	Sponsor
Collaborators:	

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: 56,385 Serial Number: 539 Has Expanded Access? No
Review Board:	Approval Status: Board Name: Board Affiliation: Phone: Email:
Data Monitoring?:	
Plan to Share Data?:	
Oversight Authorities:	United States: Food and Drug Administration Bulgaria: Bulgarian Drug Agency Denmark: Danish Medicines Agency France: Afssaps - Agence française de sécurité sanitaire des produits de santé (Saint-Denis) Hungary: National Institute of Pharmacy Italy: National Institute of Health Canada: Health Canada Romania: Ministry of Public Health Brazil: National Health Surveillance Agency Argentina: Administracion Nacional de Medicamentos, Alimentos y Tecnologia Medica Mexico: Federal Commission for Sanitary Risks Protection

Study Description

Brief Summary:	The purpose of this study is to evaluate the effects of Crestor (rosuvastatin) and (Lipitor) atorvastatin on urinary protein excretion over 1 year in patients with Type 1 or 2 diabetes with moderate proteinuria and hypercholesterolaemia.
Detailed Description:	

Conditions

Conditions:	Diabetes Mellitus
Keywords:	Hyperlipidemia Proteinuria Diabetes Mellitus

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 2
Intervention Model:	Parallel Assignment
Number of Arms:	3
Masking:	Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor)
Allocation:	Randomized
Endpoint Classification:	Safety/Efficacy Study
Enrollment:	353 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: 1 Rosuvastatin 10 mg	Drug: Rosuvastatin 10 mg oral dose administered once daily for 52 weeks Other Names: • Crestor
Experimental: 2 Rosuvastatin 40 mg	Drug: Rosuvastatin 20 mg oral dose administered once daily for 4 weeks followed by 40 mg oral dose administered once daily for 48 weeks Other Names: • Crestor
Active Comparator: 3 Atorvastatin 80 mg	Drug: Atorvastatin 40 mg oral dose administered once daily for 4 weeks followed by 80 mg oral dose administered once daily for 48 weeks Other Names: • Lipitor

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age: 18 Years

Maximum Age:

Gender: Both

Accepts Healthy Volunteers?: No

Criteria: Inclusion Criteria:

- hyperlipidemia
- urinary protein
- diabetes

Exclusion Criteria:

- previous rosuvastatin treatment < 6 months prior to Visit 1
- statin intolerance
- severe hypertension

Contacts/Locations

Study Officials: AstraZeneca Crestor Medical Science Director, MD
Study Director
AstraZeneca

Locations: Bulgaria
Research Site
Sofia, Bulgaria

Research Site
Varna, Bulgaria

Research Site
Pleven, Bulgaria

Research Site
Plovdiv, Bulgaria

Research Site
Burgas, Bulgaria

Research Site
Veliko Tarnovo, Bulgaria

Research Site
Gabrovo, Bulgaria

Denmark
Research Site
Gentofte, Denmark

Research Site
Koge, Denmark

Research Site
Hillerod, Denmark

Research Site
Aalborg, Denmark

Research Site
Farso, Denmark

Hungary
Research Site
Gyor, Hungary

Research Site
Nyiregyhaza, Hungary

Research Site
Debrecen, Hungary

Research site
Budapest, Hungary

Research site
Gyula, Hungary

Research Site
Kecskemét, Hungary

Research Site
Székesfehérvár, Hungary

Research Site
Tatabanya, Hungary

Research Site
Mosonmagyarovar, Hungary

United States, Florida
Research Site
Hollywood, Florida, United States

United States, California
Research Site
Riverside, California, United States

United States, Ohio
Research Site
Kettering, Ohio, United States

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

United States, Missouri
Research Site
St. Louis, Missouri, United States

United States, California
Research Site
West Hills, California, United States

United States, Arkansas
Research Site
Jonesboro, Arkansas, United States

United States, Pennsylvania
Research Site
Pittsburg, Pennsylvania, United States

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

United States, Texas
Research Site
San Antonio, Texas, United States

United States, Wisconsin
Research Site
Milwaukee, Wisconsin, United States

United States, North Carolina
Research Site

Winston Salem, North Carolina, United States

United States, Massachusetts
Research Site
Springfield, Massachusetts, United States

United States, New York
Research Site
Orchard Park, New York, United States

United States, Florida
Research Site
West Palm Beach, Florida, United States

United States, California
Research Site
Santa Ana, California, United States

United States, Missouri
Research Site
Columbia, Missouri, United States

United States, South Carolina
Research Site
Columbia, South Carolina, United States

Italy
Research Site
Bergamo, Italy

Research Site
Cagliari, Italy

Research Site
Milano, Italy

Research Site
Treviglio, Italy

Research Site
San Giovanni Rotondo, Italy

France
Research Site
Pessac, France

Research Site
Besançon, France

Denmark
Research Site
Hvidovre, Denmark

Research Site
Blegdamsvej 9, Denmark

France
Research Site
Annonay, France

Research Site
Bondy, France

Research Site
Corbeil Essonnes, France

Research Site
Corsept, France

Research Site
Creil Cedex, France

Research Site
La Chapelle Sur Erdre, France

Research Site
Colmar, France

Research Site
Nantes, France

Research Site
Quimper, France

Italy
Research Site
Sassari, Italy

United States, Texas
Research Site
Lubbock, Texas, United States

Research Site
Dallas, Texas, United States

United States, California
Research Site
Pasadena, California, United States

United States, Florida
Research Site
Jacksonville, Florida, United States

United States, Georgia
Research Site
Augusta, Georgia, United States

United States, Texas
Research Site
Houston, Texas, United States

United States, New York
Research Site
Stony Brook, New York, United States

United States, Utah
Research Site
Ogden, Utah, United States

Canada, British Columbia
Research Site
Vancouver, British Columbia, Canada

Canada, Ontario
Research Site
Oshawa, Ontario, Canada

Research Site
Ottawa, Ontario, Canada

Research Site
Richmond Hill, Ontario, Canada

Research Site
Scarborough, Ontario, Canada

Research Site
Thunder Bay, Ontario, Canada

Canada, Quebec
Research Site
Montreal, Quebec, Canada

Hungary
Research Site
Balatonfured, Hungary

Research Site
Hodmeztvasarhely, Hungary

Research Site
Zalaegerszeg, Hungary

Romania
Research Site
Baia Mare, Romania

Research Site
Targu Mures, Romania

Research Site
Timisoara, Romania

Research Site
Craiova, Romania

Research Site
Bucharest, Romania

Canada, Ontario
Research Site
Courtice, Ontario, Canada

Canada, Quebec
Research Site
Greenfield Park, Quebec, Canada

Canada, Ontario
Research Site
North York, Ontario, Canada

Hungary
Research Site
Debrecen, Hungary

Research Site
Szolnok, Hungary

Research Site
Keszthely, Hungary

Research Site
Baja, Hungary

Research Site
Miskolc, Hungary

France
Research Site
Grenoble Cedex, France

United States, New York
Research Site
Orchard Park, New York, United States

United States, Arizona
Research Site
Phoenix, Arizona, United States

United States, Michigan
Research Site
Detroit, Michigan, United States

United States, Arizona
Research Site
Avondale, Arizona, United States

Romania
Research Site
Brasov, Romania

Argentina
Research Site
Moron, Argentina

Research Site
Quilmes, Argentina

Research Site
Buenos Aires, Argentina

Reasearch Site
La Plata, Argentina

Brazil
Research Site
Goiania, Brazil

Research Site
Sao Paulo, Brazil

Research Site
Curitiba, Brazil

Research Site
Fortaleza, Brazil

Research Site
Recife, Brazil

Mexico
Research Site
Durango, Mexico

Research Site
Distrito Federal, Mexico

Research Site
Aguascalientes, Mexico

Research Site
San Luis Potosi, Mexico

Research Site
Zapopan, Mexico

Research Site
Saltillo, Mexico

Research Site
Guadalajara, Mexico

Research Site
Cauntla, Mexico

Romania
Research Site

Lasi, Romania

France
Research Site
Paris, France

Italy
Research Site
Acireale, CT, Italy

Research Site
Firenze, FI, Italy

Research Site
Sottomarnia Di Chioggia, VE, Italy

Research Site
Roma, RM, Italy

References

Citations:

Links: URL: http://www.astrazeneca.com/node/emailtriage.aspx
Description AstraZeneca Clinical Trial Information - Outside US

Study Data/Documents:

Study Results

Participant Flow

Recruitment Details	353 patients entered the study with Type 1 or 2 diabetes and were receiving current treatment with angiotensin converting enzyme (ACE) inhibitors and/or angiotensin receptor blockers (ARBs). The study was conducted at 147 centers in 11 countries.
Pre-Assignment Details	Patients requiring an adjustment of the ACE inhibitor and/or ARBs after Visit 1 were excluded. All 353 patients were randomized and 276 patients completed the study.

Reporting Groups

	Description
Rosuvastatin 10mg	
Rosuvastatin 40mg	
Atorvastatin 80mg	

Overall Study

	Rosuvastatin 10mg	Rosuvastatin 40mg	Atorvastatin 80mg
Started	118	124	111
Completed	93	101	82
Not Completed	25	23	29
Adverse Event	14	10	7
Withdrawal by Subject	3	5	11
Incorrect enrollment	3	3	4
Protocol Violation	1	2	3
Lost to Follow-up	3	1	1
Relocated to another state	1	0	0
Stopped drug before end of study visit	0	1	0
Nephrologist introduced ACE	0	1	0
Pregnancy	0	0	2
Not specified	0	0	1

Baseline Characteristics

Reporting Groups

	Description
Rosuvastatin 10mg	
Rosuvastatin 40mg	
Atorvastatin 80mg	

Baseline Measures

	Rosuvastatin 10mg	Rosuvastatin 40mg	Atorvastatin 80mg	Total
Number of Participants	118	124	111	353
Age, Customized [units: Participants]				
18-49 years	22	33	25	80
50-64 years	59	59	57	175
>=65 years	37	32	29	98
Gender, Male/Female [units: Participants]				
Female	43	32	33	108
Male	75	92	78	245
Estimated glomerular filtration rate [eGFR] [units: mL/min] Mean (Standard Deviation)	68.759 (24.1080)	72.644 (25.8018)	72.149 (24.8721)	71.210 (24.9455)
Urine albumin/creatinine ratio [units: mg/g] Mean (Standard Deviation)	1036.478 (730.6185)	1079.802 (725.7039)	1143.198 (779.5282)	1085.435 (743.5360)
Urine protein/creatinine ratio [units: mg/g] Mean (Standard Deviation)	1392.26 (888.3215)	1493.574 (996.0972)	1517.858 (969.7020)	1467.843 (952.0380)

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Urinary Protein/Creatinine Ratio in Patients With Type 1 or 2 Diabetes.
Measure Description	Urinary protein/creatinine ratio (mg/g) =urine protein concentration (mg/dL)/ urine creatinine concentration (g/dL). Outcome measure is the ratio of Week 52 [LOCF] urine protein/creatinine ratio over baseline urine protein/creatinine ratio.
Time Frame	Assessed at Week 52, Last observation carried forward (LOCF)
Safety Issue?	No

Analysis Population Description

[Not Specified]

Reporting Groups

	Description
Rosuvastatin 10mg	
Rosuvastatin 40mg	
Atorvastatin 80mg	

Measured Values

	Rosuvastatin 10mg	Rosuvastatin 40mg	Atorvastatin 80mg
Number of Participants Analyzed	107	116	102
Urinary Protein/Creatinine Ratio in Patients With Type 1 or 2 Diabetes. [units: mg/g] Geometric Mean (95% Confidence Interval)	1.016 (0.858 to 1.209)	0.955 (0.869 to 1.185)	0.874 (0.733 to 0.975)

2. Secondary Outcome Measure:

Measure Title	Urinary Protein/Creatinine Ratio at Week 26.
Measure Description	Urinary protein/creatinine ratio (mg/g) =urine protein concentration (mg/dL)/ urine creatinine concentration (g/dL). Outcome measure is the ratio of Week 26 urine protein/creatinine ratio over baseline urine protein/creatinine ratio.
Time Frame	Assessed at Week 26
Safety Issue?	No

Analysis Population Description

[Not Specified]

Reporting Groups

	Description
Rosuvastatin 10mg	
Rosuvastatin 40mg	
Atorvastatin 80mg	

Measured Values

	Rosuvastatin 10mg	Rosuvastatin 40mg	Atorvastatin 80mg
Number of Participants Analyzed	98	108	92

	Rosuvastatin 10mg	Rosuvastatin 40mg	Atorvastatin 80mg
Urinary Protein/Creatinine Ratio at Week 26. [units: mg/g] Geometric Mean (95% Confidence Interval)	1.007 (0.895 to 1.133)	0.994 (0.881 to 1.121)	0.876 (0.784 to 0.979)

3. Secondary Outcome Measure:

Measure Title	Urinary Albumin/Creatinine Ratio at Week 26
Measure Description	Urinary albumin/creatinine ratio (mg/g) =urine albumin concentration (mg/dL)/ urine creatinine concentration (g/dL). Outcome measure is the ratio of Week 26 urine albumin/creatinine ratio over baseline urine albumin/creatinine ratio.
Time Frame	Assessed at Week 26
Safety Issue?	No

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
Rosuvastatin 10mg	
Rosuvastatin 40mg	
Atorvastatin 80mg	

Measured Values

	Rosuvastatin 10mg	Rosuvastatin 40mg	Atorvastatin 80mg
Number of Participants Analyzed	98	109	92
Urinary Albumin/Creatinine Ratio at Week 26 [units: mg/g] Geometric Mean (95% Confidence Interval)	0.927 (0.792 to 1.085)	0.913 (0.788 to 1.058)	0.831 (0.726 to 0.951)

4. Secondary Outcome Measure:

Measure Title	Urinary Albumin/Creatinine Ratio at Week 52 [LOCF]

Measure Description	Urinary albumin/creatinine ratio (mg/g) =urine albumin concentration (mg/dL)/ urine creatinine concentration (g/dL). Outcome measure is the ratio of Week 52 [LOCF] urine albumin/creatinine ratio over baseline urine albumin/creatinine ratio.
Time Frame	Assessed at Week 52 LOCF
Safety Issue?	No

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
Rosuvastatin 10mg	
Rosuvastatin 40mg	
Atorvastatin 80mg	

Measured Values

	Rosuvastatin 10mg	Rosuvastatin 40mg	Atorvastatin 80mg
Number of Participants Analyzed	107	116	102
Urinary Albumin/Creatinine Ratio at Week 52 [LOCF] [units: mg/g] Geometric Mean (95% Confidence Interval)	1.016 (0.856 to 1.206)	0.836 (0.704 to 0.993)	0.823 (0.709 to 0.954)

5. Secondary Outcome Measure:

Measure Title	Change From Baseline in Estimated Glomerular Filtration Rate (eGFR) at Week 26
Measure Description	
Time Frame	Assessed at Baseline and Week 26
Safety Issue?	No

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
Rosuvastatin 10mg	

	Description
Rosuvastatin 40mg	
Atorvastatin 80mg	

Measured Values

	Rosuvastatin 10mg	Rosuvastatin 40mg	Atorvastatin 80mg
Number of Participants Analyzed	100	111	92
Change From Baseline in Estimated Glomerular Filtration Rate (eGFR) at Week 26 [units: mL/min] Mean (Standard Deviation)	-2.73 (12.644)	-5.46 (14.079)	-1.78 (10.997)

6. Secondary Outcome Measure:

Measure Title	Change From Baseline in eGFR at Week 52 [LOCF]
Measure Description	
Time Frame	Assessed at Baseline and Week 52 [LOCF]
Safety Issue?	No

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
Rosuvastatin 10 mg	
Rosuvastatin 40 mg	
Atorvastatin 80 mg	

Measured Values

	Rosuvastatin 10 mg	Rosuvastatin 40 mg	Atorvastatin 80 mg
Number of Participants Analyzed	107	115	101
Change From Baseline in eGFR at Week 52 [LOCF] [units: mL/min] Mean (Standard Deviation)	-3.70 (14.551)	-7.29 (20.040)	-1.61 (12.769)

7. Secondary Outcome Measure:

Measure Title	Correlation Coefficient Urinary Protein/Creatinine Ratio and Total Cholesterol [TC] Indicating the Relationship Between Renal Effects and Lipid Changes
Measure Description	Correlation of changes from baseline in urinary protein/creatinine ratio with percent change from baseline in lipids and lipoprotein concentrations at Week 52 (LOCF).
Time Frame	52 weeks
Safety Issue?	No

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
Rosuvastatin	Rosuvastatin Treatments pooled
Atorvastatin	Atorvastatin Treatment
All Treatment	All Treatments pooled

Measured Values

	Rosuvastatin	Atorvastatin	All Treatment
Number of Participants Analyzed	205	91	296
Correlation Coefficient Urinary Protein/Creatinine Ratio and Total Cholesterol [TC] Indicating the Relationship Between Renal Effects and Lipid Changes [units: Correlation coefficient]	-0.03507	0.14258	0.01600

8. Secondary Outcome Measure:

Measure Title	Relationship Between Renal Effects and Lipid Changes: Urinary Protein/Creatinine Ratio TC
Measure Description	Correlation of changes from baseline in urinary protein/creatinine ratio with percent change from baseline in lipids and lipoprotein concentrations at Week 52
Time Frame	Assessed at 52 Weeks

Safety Issue?	No

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
Rosuvastatin	Rosuvastatin Treatments pooled
Atorvastatin	Atorvastatin Treatment
All Treatment	All Treatments pooled

Measured Values

	Rosuvastatin	Atorvastatin	All Treatment
Number of Participants Analyzed	190	79	269
Relationship Between Renal Effects and Lipid Changes: Urinary Protein/Creatinine Ratio TC [units: Correlation coefficient]	0.07019	0.26855	0.12013

9. Secondary Outcome Measure:

Measure Title	Relationship Between Renal Effects and Lipid Changes: Urinary Protein/Creatinine Ratio and Low Density Lipoprotein Cholesterol [LDL-C]
Measure Description	Correlation of changes from baseline in urinary protein/creatinine ratio with percent change from baseline in lipids and lipoprotein concentrations at Week 26.
Time Frame	26 weeks
Safety Issue?	No

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
Rosuvastatin	Rosuvastatin Treatments pooled
Atorvastatin	Atorvastatin Treatment

	Description
All Treatment	All Treatments pooled

Measured Values

	Rosuvastatin	Atorvastatin	All Treatment
Number of Participants Analyzed	203	90	293
Relationship Between Renal Effects and Lipid Changes: Urinary Protein/Creatinine Ratio and Low Density Lipoprotein Cholesterol [LDL-C] [units: Correlation coefficient]	-0.08588	0.18570	-0.02491

10. Secondary Outcome Measure:

Measure Title	Relationship Between Renal Effects and Lipid Changes: Urinary Protein/Creatinine Ratio and LDL-C
Measure Description	Correlation of changes from baseline in urinary protein/creatinine ratio with percent change from baseline in lipids and lipoprotein concentrations at Week 52
Time Frame	52 Weeks
Safety Issue?	No

Analysis Population Description

[Not Specified]

Reporting Groups

	Description
Rosuvastatin	Rosuvastatin Treatments pooled
Atorvastatin	Atorvastatin Treatment
All Treatment	All Treatments pooled

Measured Values

	Rosuvastatin	Atorvastatin	All Treatment
Number of Participants Analyzed	190	78	268
Relationship Between Renal Effects and Lipid Changes: Urinary Protein/Creatinine Ratio and LDL-C [units: Correlation coefficient]	0.04510	0.16280	0.06739

11. Secondary Outcome Measure:

Measure Title	Relationship Between Renal Effects and Lipid Changes: Urinary Protein/Creatinine Ratio and High Density Lipoprotein Cholesterol [HDL-C]
Measure Description	Correlation of changes from baseline in urinary protein/creatinine ratio with percent change from baseline in lipids and lipoprotein concentrations at Week 26.
Time Frame	26 weeks
Safety Issue?	No

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
Rosuvastatin	Rosuvastatin Treatments pooled
Atorvastatin	Atorvastatin Treatment
All Treatment	All Treatments pooled

Measured Values

	Rosuvastatin	Atorvastatin	All Treatment
Number of Participants Analyzed	203	90	293
Relationship Between Renal Effects and Lipid Changes: Urinary Protein/Creatinine Ratio and High Density Lipoprotein Cholesterol [HDL-C] [units: Correlation coefficient]	0.15614	0.06987	0.14226

12. Secondary Outcome Measure:

Measure Title	Relationship Between Renal Effects and Lipid Changes: Urinary Protein/Creatinine Ratio and HDL-C
Measure Description	Correlation of changes from baseline in urinary protein/creatinine ratio with percent change from baseline in lipids and lipoprotein concentrations at Week 52
Time Frame	52 Weeks
Safety Issue?	No

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
Rosuvastatin	Rosuvastatin Treatments pooled
Atorvastatin	Atorvastatin Treatment
All Treatment	All Treatments pooled

Measured Values

	Rosuvastatin	Atorvastatin	All Treatment
Number of Participants Analyzed	190	78	268
Relationship Between Renal Effects and Lipid Changes: Urinary Protein/Creatinine Ratio and HDL-C [units: Correlation coefficient]	0.16111	0.26194	0.18918

13. Secondary Outcome Measure:

Measure Title	Relationship Between Renal Effects and Lipid Changes: Urinary Protein/Creatinine Ratio and Non-high Density Lipoprotein Cholesterol [nonHDL-C]
Measure Description	Correlation of changes from baseline in urinary protein/creatinine ratio with percent change from baseline in lipids and lipoprotein concentrations at Week 26.
Time Frame	26 weeks
Safety Issue?	No

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
Rosuvastatin	Rosuvastatin Treatments pooled
Atorvastatin	Atorvastatin Treatment
All Treatment	All Treatments pooled

Measured Values

	Rosuvastatin	Atorvastatin	All Treatment
Number of Participants Analyzed	203	90	293
Relationship Between Renal Effects and Lipid Changes: Urinary Protein/Creatinine Ratio and Non-high Density Lipoprotein Cholesterol [nonHDL-C] [units: Correlation coefficient]	-0.12068	0.15929	-0.05186

14. Secondary Outcome Measure:

Measure Title	Relationship Between Renal Effects and Lipid Changes: Urinary Protein/Creatinine Ratio and nonHDL-C
Measure Description	Correlation of changes from baseline in urinary protein/creatinine ratio with percent change from baseline in lipids and lipoprotein concentrations at Week 52
Time Frame	52 Weeks
Safety Issue?	No

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
Rosuvastatin	Rosuvastatin Treatments pooled
Atorvastatin	Atorvastatin Treatment
All Treatment	All Treatments pooled

Measured Values

	Rosuvastatin	Atorvastatin	All Treatment
Number of Participants Analyzed	190	78	268
Relationship Between Renal Effects and Lipid Changes: Urinary Protein/Creatinine Ratio and nonHDL-C [units: Correlation coefficient]	0.02594	0.24018	0.07381

15. Secondary Outcome Measure:

Measure Title	Relationship Between Renal Effects and Lipid Changes: Urinary Protein/Creatinine Ratio and Triglyceride [TG]
Measure Description	Correlation of changes from baseline in urinary protein/creatinine ratio with percent change from baseline in lipids and lipoprotein concentrations at Week 26.
Time Frame	26 weeks
Safety Issue?	No

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
Rosuvastatin	Rosuvastatin Treatments pooled
Atorvastatin	Atorvastatin Treatment
All Treatment	All Treatments pooled

Measured Values

	Rosuvastatin	Atorvastatin	All Treatment
Number of Participants Analyzed	205	91	296
Relationship Between Renal Effects and Lipid Changes: Urinary Protein/Creatinine Ratio and Triglyceride [TG] [units: Correlation coefficient]	-0.14569	0.04948	-0.08471

16. Secondary Outcome Measure:

Measure Title	Relationship Between Renal Effects and Lipid Changes: Urinary Protein/Creatinine Ratio and TG
Measure Description	Correlation of changes from baseline in urinary protein/creatinine ratio with percent change from baseline in lipids and lipoprotein concentrations at Week 52
Time Frame	52 Weeks
Safety Issue?	No

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
Rosuvastatin	Rosuvastatin Treatments pooled
Atorvastatin	Atorvastatin Treatment
All Treatment	All Treatments pooled

Measured Values

	Rosuvastatin	Atorvastatin	All Treatment
Number of Participants Analyzed	190	78	269
Relationship Between Renal Effects and Lipid Changes: Urinary Protein/Creatinine Ratio and TG [units: Correlation coefficient]	-0.05251	0.11755	0.01345

17. Secondary Outcome Measure:

Measure Title	Relationship Between Renal Effects and Lipid Changes: Urinary Protein/Creatinine Ratio and TC/HDL-C Ratio
Measure Description	Correlation of changes from baseline in urinary protein/creatinine ratio with percent change from baseline in lipids and lipoprotein concentrations at Week 26.
Time Frame	26 weeks
Safety Issue?	No

Analysis Population Description

[Not Specified]

Reporting Groups

	Description
Rosuvastatin	Rosuvastatin Treatments pooled
Atorvastatin	Atorvastatin Treatment
All Treatment	All Treatments pooled

Measured Values

	Rosuvastatin	Atorvastatin	All Treatment
Number of Participants Analyzed	203	90	293

	Rosuvastatin	Atorvastatin	All Treatment
Relationship Between Renal Effects and Lipid Changes: Urinary Protein/Creatinine Ratio and TC/HDL-C Ratio [units: Correlation coefficient]	-0.13572	0.07339	-0.08855

18. Secondary Outcome Measure:

Measure Title	Relationship Between Renal Effects and Lipid Changes: Urinary Protein/Creatinine Ratio and TC/HDL-C Ratio
Measure Description	Correlation of changes from baseline in urinary protein/creatinine ratio with percent change from baseline in lipids and lipoprotein concentrations at Week 52
Time Frame	52 Weeks
Safety Issue?	No

Analysis Population Description

[Not Specified]

Reporting Groups

	Description
Rosuvastatin	Rosuvastatin Treatments pooled
Atorvastatin	Atorvastatin Treatment
All Treatment	All Treatments pooled

Measured Values

	Rosuvastatin	Atorvastatin	All Treatment
Number of Participants Analyzed	190	78	268
Relationship Between Renal Effects and Lipid Changes: Urinary Protein/Creatinine Ratio and TC/HDL-C Ratio [units: Correlation coefficient]	-0.05945	0.12132	-0.02666

19. Secondary Outcome Measure:

Measure Title	Relationship Between Renal Effects and Lipid Changes: Urinary Protein/Creatinine Ratio and LDL-C/HDL-C Ratio

Measure Description	Correlation of changes from baseline in urinary protein/creatinine ratio with percent change from baseline in lipids and lipoprotein concentrations at Week 26.
Time Frame	26 weeks
Safety Issue?	No

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
Rosuvastatin	Rosuvastatin Treatments pooled
Atorvastatin	Atorvastatin Treatment
All Treatment	All Treatments pooled

Measured Values

	Rosuvastatin	Atorvastatin	All Treatment
Number of Participants Analyzed	203	90	293
Relationship Between Renal Effects and Lipid Changes: Urinary Protein/Creatinine Ratio and LDL-C/HDL-C Ratio [units: Correlation coefficient]	-0.13689	0.12931	-0.08108

20. Secondary Outcome Measure:

Measure Title	Relationship Between Renal Effects and Lipid Changes: Urinary Protein/Creatinine Ratio and LDL-C/HDL-C Ratio
Measure Description	Correlation of changes from baseline in urinary protein/creatinine ratio with percent change from baseline in lipids and lipoprotein concentrations at Week 52
Time Frame	52 Weeks
Safety Issue?	No

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
Rosuvastatin	Rosuvastatin Treatments pooled
Atorvastatin	Atorvastatin Treatment
All Treatment	All Treatments pooled

Measured Values

	Rosuvastatin	Atorvastatin	All Treatment
Number of Participants Analyzed	190	78	268
Relationship Between Renal Effects and Lipid Changes: Urinary Protein/Creatinine Ratio and LDL-C/HDL-C Ratio [units: Correlation coefficient]	-0.02775	0.06535	-0.01569

21. Secondary Outcome Measure:

Measure Title	Relationship Between Renal Effects and Lipid Changes: Urinary Protein/Creatinine Ratio and nonHDL-C/HDL-C Ratio
Measure Description	Correlation of changes from baseline in urinary protein/creatinine ratio with percent change from baseline in lipids and lipoprotein concentrations at Week 26.
Time Frame	26 weeks
Safety Issue?	No

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
Rosuvastatin	Rosuvastatin Treatments pooled
Atorvastatin	Atorvastatin Treatment
All Treatment	All Treatments pooled

Measured Values

	Rosuvastatin	Atorvastatin	All Treatment
Number of Participants Analyzed	203	90	293

	Rosuvastatin	Atorvastatin	All Treatment
Relationship Between Renal Effects and Lipid Changes: Urinary Protein/Creatinine Ratio and nonHDL-C/HDL-C Ratio [units: Correlation coefficient]	-0.16755	0.08891	-0.11221

22. Secondary Outcome Measure:

Measure Title	Relationship Between Renal Effects and Lipid Changes: Urinary Protein/Creatinine Ratio and nonHDL-C/HDL-C Ratio
Measure Description	Correlation of changes from baseline in urinary protein/creatinine ratio with percent change from baseline in lipids and lipoprotein concentrations at Week 52
Time Frame	52 Weeks
Safety Issue?	No

Analysis Population Description

[Not Specified]

Reporting Groups

	Description
Rosuvastatin	Rosuvastatin Treatments pooled
Atorvastatin	Atorvastatin Treatment
All Treatment	All Treatments pooled

Measured Values

	Rosuvastatin	Atorvastatin	All Treatment
Number of Participants Analyzed	190	78	268
Relationship Between Renal Effects and Lipid Changes: Urinary Protein/Creatinine Ratio and nonHDL-C/HDL-C Ratio [units: Correlation coefficient]	-0.06085	0.12507	-0.02841

23. Secondary Outcome Measure:

Measure Title	Relationship Between Renal Effects and Lipid Changes: Urinary Protein/Creatinine Ratio and Apolipoprotein A-1 [ApoA-1]
Measure Description	Correlation of changes from baseline in urinary protein/creatinine ratio with percent change from baseline in lipids and lipoprotein concentrations at Week 26.
Time Frame	26 weeks
Safety Issue?	No

Analysis Population Description

[Not Specified]

Reporting Groups

	Description
Rosuvastatin	Rosuvastatin Treatments pooled
Atorvastatin	Atorvastatin Treatment
All Treatment	All Treatments pooled

Measured Values

	Rosuvastatin	Atorvastatin	All Treatment
Number of Participants Analyzed	191	87	278
Relationship Between Renal Effects and Lipid Changes: Urinary Protein/Creatinine Ratio and Apolipoprotein A-1 [ApoA-1] [units: Correlation coefficient]	0.15859	0.13133	0.15516

24. Secondary Outcome Measure:

Measure Title	Relationship Between Renal Effects and Lipid Changes: Urinary Protein/Creatinine Ratio and ApoA-1
Measure Description	Correlation of changes from baseline in urinary protein/creatinine ratio with percent change from baseline in lipids and lipoprotein concentrations at Week 52
Time Frame	52 Weeks
Safety Issue?	No

Analysis Population Description

[Not Specified]

Reporting Groups

	Description
Rosuvastatin	Rosuvastatin Treatments pooled
Atorvastatin	Atorvastatin Treatment
All Treatment	All Treatments pooled

Measured Values

	Rosuvastatin	Atorvastatin	All Treatment
Number of Participants Analyzed	183	78	261
Relationship Between Renal Effects and Lipid Changes: Urinary Protein/Creatinine Ratio and ApoA-1 [units: Correlation coefficient]	0.16587	0.18469	0.18832

25. Secondary Outcome Measure:

Measure Title	Relationship Between Renal Effects and Lipid Changes: Urinary Protein/Creatinine Ratio and Apolipoprotein B [ApoB]
Measure Description	Correlation of changes from baseline in urinary protein/creatinine ratio with percent change from baseline in lipids and lipoprotein concentrations at Week 26.
Time Frame	26 weeks
Safety Issue?	No

Analysis Population Description

[Not Specified]

Reporting Groups

	Description
Rosuvastatin	Rosuvastatin Treatments pooled
Atorvastatin	Atorvastatin Treatment
All Treatment	All Treatments pooled

Measured Values

	Rosuvastatin	Atorvastatin	All Treatment
Number of Participants Analyzed	191	87	278
Relationship Between Renal Effects and Lipid Changes: Urinary Protein/Creatinine Ratio and Apolipoprotein B [ApoB] [units: Correlation coefficient]	-0.02276	0.21405	0.04578

26. Secondary Outcome Measure:

Measure Title	Relationship Between Renal Effects and Lipid Changes: Urinary Protein/Creatinine Ratio and ApoB
Measure Description	Correlation of changes from baseline in urinary protein/creatinine ratio with percent change from baseline in lipids and lipoprotein concentrations at Week 52
Time Frame	52 Weeks
Safety Issue?	No

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
Rosuvastatin	Rosuvastatin Treatments pooled
Atorvastatin	Atorvastatin Treatment
All Treatment	All Treatments pooled

Measured Values

	Rosuvastatin	Atorvastatin	All Treatment
Number of Participants Analyzed	183	78	261
Relationship Between Renal Effects and Lipid Changes: Urinary Protein/Creatinine Ratio and ApoB [units: Correlation coefficient]	0.05397	0.29486	0.11079

27. Secondary Outcome Measure:

Measure Title	Relationship Between Renal Effects and Lipid Changes: Urinary Protein/Creatinine Ratio and ApoB/ApoA-1 Ratio
Measure Description	Correlation of changes from baseline in urinary protein/creatinine ratio with percent change from baseline in lipids and lipoprotein concentrations at Week 26.
Time Frame	26 weeks
Safety Issue?	No

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
Rosuvastatin	Rosuvastatin Treatments pooled
Atorvastatin	Atorvastatin Treatment
All Treatment	All Treatments pooled

Measured Values

	Rosuvastatin	Atorvastatin	All Treatment
Number of Participants Analyzed	191	87	278
Relationship Between Renal Effects and Lipid Changes: Urinary Protein/Creatinine Ratio and ApoB/ApoA-1 Ratio [units: Correlation coefficient]	-0.07846	0.13910	-0.02825

28. Secondary Outcome Measure:

Measure Title	Relationship Between Renal Effects and Lipid Changes: Urinary Protein/Creatinine Ratio and ApoB/ApoA-1 Ratio
Measure Description	Correlation of changes from baseline in urinary protein/creatinine ratio with percent change from baseline in lipids and lipoprotein concentrations at Week 52
Time Frame	52 Weeks
Safety Issue?	No

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
Rosuvastatin	Rosuvastatin Treatments pooled
Atorvastatin	Atorvastatin Treatment
All Treatment	All Treatments pooled

Measured Values

	Rosuvastatin	Atorvastatin	All Treatment
Number of Participants Analyzed	183	78	261
Relationship Between Renal Effects and Lipid Changes: Urinary Protein/Creatinine Ratio and ApoB/ ApoA-1 Ratio [units: Correlation coefficient]	0.00600	0.22710	0.03684

29. Secondary Outcome Measure:

Measure Title	Relationship Between Renal Effects and Lipid Changes: Urinary Albumin/Creatinine Ratio and TC
Measure Description	Correlation of changes from baseline in urinary albumin/creatinine ratio with percent change from baseline in lipids and lipoprotein concentrations at Week 26.
Time Frame	26 weeks
Safety Issue?	No

Analysis Population Description

[Not Specified]

Reporting Groups

	Description
Rosuvastatin	Rosuvastatin Treatments pooled
Atorvastatin	Atorvastatin Treatment
All Treatment	All Treatments pooled

Measured Values

	Rosuvastatin	Atorvastatin	All Treatment
Number of Participants Analyzed	206	91	297

	Rosuvastatin	Atorvastatin	All Treatment
Relationship Between Renal Effects and Lipid Changes: Urinary Albumin/Creatinine Ratio and TC [units: Correlation coefficient]	0.00642	0.14331	0.04311

30. Secondary Outcome Measure:

Measure Title	Relationship Between Renal Effects and Lipid Changes: Urinary Albumin/Creatinine Ratio and TC
Measure Description	Correlation of changes from baseline in urinary albumin/creatinine ratio with percent change from baseline in lipids and lipoprotein concentrations at Week 52
Time Frame	52 Weeks
Safety Issue?	No

Analysis Population Description

[Not Specified]

Reporting Groups

	Description
Rosuvastatin	Rosuvastatin Treatments pooled
Atorvastatin	Atorvastatin Treatment
All Treatment	All Treatments pooled

Measured Values

	Rosuvastatin	Atorvastatin	All Treatment
Number of Participants Analyzed	191	79	270
Relationship Between Renal Effects and Lipid Changes: Urinary Albumin/Creatinine Ratio and TC [units: Correlation coefficient]	0.13220	0.35715	0.18971

31. Secondary Outcome Measure:

Measure Title	Relationship Between Renal Effects and Lipid Changes: Urinary Albumin/Creatinine Ratio and LDL-C

Measure Description	Correlation of changes from baseline in urinary albumin/creatinine ratio with percent change from baseline in lipids and lipoprotein concentrations at Week 26.
Time Frame	26 weeks
Safety Issue?	No

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
Rosuvastatin	Rosuvastatin Treatments pooled
Atorvastatin	Atorvastatin Treatment
All Treatment	All Treatments pooled

Measured Values

	Rosuvastatin	Atorvastatin	All Treatment
Number of Participants Analyzed	204	90	294
Relationship Between Renal Effects and Lipid Changes: Urinary Albumin/Creatinine Ratio and LDL-C [units: Correlation coefficient]	-0.05514	0.19842	0.00038

32. Secondary Outcome Measure:

Measure Title	Relationship Between Renal Effects and Lipid Changes: Urinary Albumin/Creatinine Ratio and LDL-C
Measure Description	Correlation of changes from baseline in urinary albumin/creatinine ratio with percent change from baseline in lipids and lipoprotein concentrations at Week 52
Time Frame	52 Weeks
Safety Issue?	No

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
Rosuvastatin	Rosuvastatin Treatments pooled
Atorvastatin	Atorvastatin Treatment
All Treatment	All Treatments pooled

Measured Values

	Rosuvastatin	Atorvastatin	All Treatment
Number of Participants Analyzed	191	78	269
Relationship Between Renal Effects and Lipid Changes: Urinary Albumin/Creatinine Ratio and LDL-C [units: Correlation coefficient]	0.10037	0.21205	0.12270

33. Secondary Outcome Measure:

Measure Title	Relationship Between Renal Effects and Lipid Changes: Urinary Albumin/Creatinine Ratio and HDL-C
Measure Description	Correlation of changes from baseline in urinary albumin/creatinine ratio with percent change from baseline in lipids and lipoprotein concentrations at Week 26.
Time Frame	26 weeks
Safety Issue?	No

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
Rosuvastatin	Rosuvastatin Treatments pooled
Atorvastatin	Atorvastatin Treatment
All Treatment	All Treatments pooled

Measured Values

	Rosuvastatin	Atorvastatin	All Treatment
Number of Participants Analyzed	204	90	294

	Rosuvastatin	Atorvastatin	All Treatment
Relationship Between Renal Effects and Lipid Changes: Urinary Albumin/Creatinine Ratio and HDL-C [units: Correlation coefficient]	0.08593	0.00032	0.06930

34. Secondary Outcome Measure:

Measure Title	Relationship Between Renal Effects and Lipid Changes: Urinary Albumin/Creatinine Ratio and HDL-C
Measure Description	Correlation of changes from baseline in urinary albumin/creatinine ratio with percent change from baseline in lipids and lipoprotein concentrations at Week 52
Time Frame	52 Weeks
Safety Issue?	No

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
Rosuvastatin	Rosuvastatin Treatments pooled
Atorvastatin	Atorvastatin Treatment
All Treatment	All Treatments pooled

Measured Values

	Rosuvastatin	Atorvastatin	All Treatment
Number of Participants Analyzed	191	78	269
Relationship Between Renal Effects and Lipid Changes: Urinary Albumin/Creatinine Ratio and HDL-C [units: Correlation coefficient]	0.14758	0.26805	0.17550

35. Secondary Outcome Measure:

Measure Title	Relationship Between Renal Effects and Lipid Changes: Urinary Albumin/Creatinine Ratio and nonHDL-C

Measure Description	Correlation of changes from baseline in urinary albumin/creatinine ratio with percent change from baseline in lipids and lipoprotein concentrations at Week 26.
Time Frame	26 weeks
Safety Issue?	No

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
Rosuvastatin	Rosuvastatin Treatments pooled
Atorvastatin	Atorvastatin Treatment
All Treatment	All Treatments pooled

Measured Values

	Rosuvastatin	Atorvastatin	All Treatment
Number of Participants Analyzed	204	90	294
Relationship Between Renal Effects and Lipid Changes: Urinary Albumin/Creatinine Ratio and nonHDL-C [units: Correlation coefficient]	-0.06694	0.17296	-0.01144

36. Secondary Outcome Measure:

Measure Title	Relationship Between Renal Effects and Lipid Changes: Urinary Albumin/Creatinine Ratio and nonHDL-C
Measure Description	Correlation of changes from baseline in urinary albumin/creatinine ratio with percent change from baseline in lipids and lipoprotein concentrations at Week 52
Time Frame	52 Weeks
Safety Issue?	No

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
Rosuvastatin	Rosuvastatin Treatments pooled
Atorvastatin	Atorvastatin Treatment
All Treatment	All Treatments pooled

Measured Values

	Rosuvastatin	Atorvastatin	All Treatment
Number of Participants Analyzed	191	78	269
Relationship Between Renal Effects and Lipid Changes: Urinary Albumin/Creatinine Ratio and nonHDL-C [units: Correlation coefficient]	0.09189	0.33769	0.14988

37. Secondary Outcome Measure:

Measure Title	Relationship Between Renal Effects and Lipid Changes: Urinary Albumin/Creatinine Ratio and TG
Measure Description	Correlation of changes from baseline in urinary albumin/creatinine ratio with percent change from baseline in lipids and lipoprotein concentrations at Week 26.
Time Frame	26 weeks
Safety Issue?	No

Analysis Population Description

[Not Specified]

Reporting Groups

	Description
Rosuvastatin	Rosuvastatin Treatments pooled
Atorvastatin	Atorvastatin Treatment
All Treatment	All Treatments pooled

Measured Values

	Rosuvastatin	Atorvastatin	All Treatment
Number of Participants Analyzed	206	91	297

	Rosuvastatin	Atorvastatin	All Treatment
Relationship Between Renal Effects and Lipid Changes: Urinary Albumin/Creatinine Ratio and TG [units: Correlation coefficient]	-0.07271	0.08654	-0.02876

38. Secondary Outcome Measure:

Measure Title	Relationship Between Renal Effects and Lipid Changes: Urinary Albumin/Creatinine Ratio and TG
Measure Description	Correlation of changes from baseline in urinary albumin/creatinine ratio with percent change from baseline in lipids and lipoprotein concentrations at Week 52
Time Frame	52 Weeks
Safety Issue?	No

Analysis Population Description

[Not Specified]

Reporting Groups

	Description
Rosuvastatin	Rosuvastatin Treatments pooled
Atorvastatin	Atorvastatin Treatment
All Treatment	All Treatments pooled

Measured Values

	Rosuvastatin	Atorvastatin	All Treatment
Number of Participants Analyzed	191	79	270
Relationship Between Renal Effects and Lipid Changes: Urinary Albumin/Creatinine Ratio and TG [units: Correlation coefficient]	-0.02947	0.27198	0.08787

39. Secondary Outcome Measure:

Measure Title	Relationship Between Renal Effects and Lipid Changes: Urinary Albumin/Creatinine Ratio and TC/HDL-C Ratio

Measure Description	Correlation of changes from baseline in urinary albumin/creatinine ratio with percent change from baseline in lipids and lipoprotein concentrations at Week 26.
Time Frame	26 weeks
Safety Issue?	No

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
Rosuvastatin	Rosuvastatin Treatments pooled
Atorvastatin	Atorvastatin Treatment
All Treatment	All Treatments pooled

Measured Values

	Rosuvastatin	Atorvastatin	All Treatment
Number of Participants Analyzed	204	90	294
Relationship Between Renal Effects and Lipid Changes: Urinary Albumin/Creatinine Ratio and TC/HDL-C Ratio [units: Correlation coefficient]	-0.04785	0.11256	-0.01362

40. Secondary Outcome Measure:

Measure Title	Relationship Between Renal Effects and Lipid Changes: Urinary Albumin/Creatinine Ratio and TC/HDL-C Ratio
Measure Description	Correlation of changes from baseline in urinary albumin/creatinine ratio with percent change from baseline in lipids and lipoprotein concentrations at Week 52
Time Frame	52 Weeks
Safety Issue?	No

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
Rosuvastatin	Rosuvastatin Treatments pooled
Atorvastatin	Atorvastatin Treatment
All Treatment	All Treatments pooled

Measured Values

	Rosuvastatin	Atorvastatin	All Treatment
Number of Participants Analyzed	191	78	269
Relationship Between Renal Effects and Lipid Changes: Urinary Albumin/Creatinine Ratio and TC/HDL-C Ratio [units: Correlation coefficient]	0.01798	0.20127	0.05369

41. Secondary Outcome Measure:

Measure Title	Relationship Between Renal Effects and Lipid Changes: Urinary Albumin/Creatinine Ratio and LDL-C/HDL-C Ratio
Measure Description	Correlation of changes from baseline in urinary albumin/creatinine ratio with percent change from baseline in lipids and lipoprotein concentrations at Week 26.
Time Frame	26 weeks
Safety Issue?	No

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
Rosuvastatin	Rosuvastatin Treatments pooled
Atorvastatin	Atorvastatin Treatment
All Treatment	All Treatments pooled

Measured Values

	Rosuvastatin	Atorvastatin	All Treatment
Number of Participants Analyzed	204	90	294

	Rosuvastatin	Atorvastatin	All Treatment
Relationship Between Renal Effects and Lipid Changes: Urinary Albumin/Creatinine Ratio and LDL-C/HDL-C Ratio [units: Correlation coefficient]	-0.08211	0.16654	-0.03001

42. Secondary Outcome Measure:

Measure Title	Relationship Between Renal Effects and Lipid Changes: Urinary Albumin/Creatinine Ratio and LDL-C/HDL-C Ratio
Measure Description	Correlation of changes from baseline in urinary albumin/creatinine ratio with percent change from baseline in lipids and lipoprotein concentrations at Week 52
Time Frame	52 Weeks
Safety Issue?	No

Analysis Population Description

[Not Specified]

Reporting Groups

	Description
Rosuvastatin	Rosuvastatin Treatments pooled
Atorvastatin	Atorvastatin Treatment
All Treatment	All Treatments pooled

Measured Values

	Rosuvastatin	Atorvastatin	All Treatment
Number of Participants Analyzed	191	78	269
Relationship Between Renal Effects and Lipid Changes: Urinary Albumin/Creatinine Ratio and LDL-C/HDL-C Ratio [units: Correlation coefficient]	0.03476	0.10902	0.04508

43. Secondary Outcome Measure:

Measure Title	Relationship Between Renal Effects and Lipid Changes: Urinary Albumin/Creatinine Ratio and nonHDL-C/HDL-C Ratio

Measure Description	Correlation of changes from baseline in urinary albumin/creatinine ratio with percent change from baseline in lipids and lipoprotein concentrations at Week 26.
Time Frame	26 weeks
Safety Issue?	No

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
Rosuvastatin	Rosuvastatin Treatments pooled
Atorvastatin	Atorvastatin Treatment
All Treatment	All Treatments pooled

Measured Values

	Rosuvastatin	Atorvastatin	All Treatment
Number of Participants Analyzed	204	90	294
Relationship Between Renal Effects and Lipid Changes: Urinary Albumin/Creatinine Ratio and nonHDL-C/HDL-C Ratio [units: Correlation coefficient]	-0.08468	0.12805	-0.04102

44. Secondary Outcome Measure:

Measure Title	Relationship Between Renal Effects and Lipid Changes: Urinary Albumin/Creatinine Ratio and nonHDL-C/HDL-C Ratio
Measure Description	Correlation of changes from baseline in urinary albumin/creatinine ratio with percent change from baseline in lipids and lipoprotein concentrations at Week 52
Time Frame	52 Weeks
Safety Issue?	No

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
Rosuvastatin	Rosuvastatin Treatments pooled
Atorvastatin	Atorvastatin Treatment
All Treatment	All Treatments pooled

Measured Values

	Rosuvastatin	Atorvastatin	All Treatment
Number of Participants Analyzed	191	78	269
Relationship Between Renal Effects and Lipid Changes: Urinary Albumin/Creatinine Ratio and nonHDL-C/HDL-C Ratio [units: Correlation coefficient]	0.01528	0.21198	0.05251

45. Secondary Outcome Measure:

Measure Title	Relationship Between Renal Effects and Lipid Changes: Urinary Albumin/Creatinine Ratio and ApoA-1
Measure Description	Correlation of changes from baseline in urinary albumin/creatinine ratio with percent change from baseline in lipids and lipoprotein concentrations at Week 26.
Time Frame	26 weeks
Safety Issue?	No

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
Rosuvastatin	Rosuvastatin Treatments pooled
Atorvastatin	Atorvastatin Treatment
All Treatment	All Treatments pooled

Measured Values

	Rosuvastatin	Atorvastatin	All Treatment
Number of Participants Analyzed	192	87	279

	Rosuvastatin	Atorvastatin	All Treatment
Relationship Between Renal Effects and Lipid Changes: Urinary Albumin/Creatinine Ratio and ApoA-1 [units: Correlation coefficient]	0.14207	0.11171	0.13429

46. Secondary Outcome Measure:

Measure Title	Relationship Between Renal Effects and Lipid Changes: Urinary Albumin/Creatinine Ratio and ApoA-1
Measure Description	Correlation of changes from baseline in urinary albumin/creatinine ratio with percent change from baseline in lipids and lipoprotein concentrations at Week 52
Time Frame	52 Weeks
Safety Issue?	No

Analysis Population Description

[Not Specified]

Reporting Groups

	Description
Rosuvastatin	Rosuvastatin Treatments pooled
Atorvastatin	Atorvastatin Treatment
All Treatment	All Treatments pooled

Measured Values

	Rosuvastatin	Atorvastatin	All Treatment
Number of Participants Analyzed	184	78	262
Relationship Between Renal Effects and Lipid Changes: Urinary Albumin/Creatinine Ratio and ApoA-1 [units: Correlation coefficient]	0.16085	0.15933	0.17306

47. Secondary Outcome Measure:

Measure Title	Relationship Between Renal Effects and Lipid Changes: Urinary Albumin/Creatinine Ratio and ApoB

Measure Description	Correlation of changes from baseline in urinary albumin/creatinine ratio with percent change from baseline in lipids and lipoprotein concentrations at Week 26.
Time Frame	26 weeks
Safety Issue?	No

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
Rosuvastatin	Rosuvastatin Treatments pooled
Atorvastatin	Atorvastatin Treatment
All Treatment	All Treatments pooled

Measured Values

	Rosuvastatin	Atorvastatin	All Treatment
Number of Participants Analyzed	192	87	279
Relationship Between Renal Effects and Lipid Changes: Urinary Albumin/Creatinine Ratio and ApoB [units: Correlation coefficient]	-0.00569	0.20008	0.04833

48. Secondary Outcome Measure:

Measure Title	Relationship Between Renal Effects and Lipid Changes: Urinary Albumin/Creatinine Ratio and ApoB
Measure Description	Correlation of changes from baseline in urinary albumin/creatinine ratio with percent change from baseline in lipids and lipoprotein concentrations at Week 52
Time Frame	52 Weeks
Safety Issue?	No

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
Rosuvastatin	Rosuvastatin Treatments pooled
Atorvastatin	Atorvastatin Treatment
All Treatment	All Treatments pooled

Measured Values

	Rosuvastatin	Atorvastatin	All Treatment
Number of Participants Analyzed	184	78	262
Relationship Between Renal Effects and Lipid Changes: Urinary Albumin/Creatinine Ratio and ApoB [units: Correlation coefficient]	0.10997	0.30537	0.15652

49. Secondary Outcome Measure:

Measure Title	Relationship Between Renal Effects and Lipid Changes: Urinary Albumin/Creatinine Ratio and ApoB/ApoA-1 Ratio
Measure Description	Correlation of changes from baseline in urinary albumin/creatinine ratio with percent change from baseline in lipids and lipoprotein concentrations at Week 26.
Time Frame	26 weeks
Safety Issue?	No

Analysis Population Description

[Not Specified]

Reporting Groups

	Description
Rosuvastatin	Rosuvastatin Treatments pooled
Atorvastatin	Atorvastatin Treatment
All Treatment	All Treatments pooled

Measured Values

	Rosuvastatin	Atorvastatin	All Treatment
Number of Participants Analyzed	192	87	279

	Rosuvastatin	Atorvastatin	All Treatment
Relationship Between Renal Effects and Lipid Changes: Urinary Albumin/Creatinine Ratio and ApoB/ApoA-1 Ratio [units: Correlation coefficient]	-0.05906	0.13706	-0.01775

50. Secondary Outcome Measure:

Measure Title	Relationship Between Renal Effects and Lipid Changes: Urinary Albumin/Creatinine Ratio and ApoB/ApoA-1 Ratio
Measure Description	Correlation of changes from baseline in urinary albumin/creatinine ratio with percent change from baseline in lipids and lipoprotein concentrations at Week 52
Time Frame	52 Weeks
Safety Issue?	No

Analysis Population Description

[Not Specified]

Reporting Groups

	Description
Rosuvastatin	Rosuvastatin Treatments pooled
Atorvastatin	Atorvastatin Treatment
All Treatment	All Treatments pooled

Measured Values

	Rosuvastatin	Atorvastatin	All Treatment
Number of Participants Analyzed	184	78	262
Relationship Between Renal Effects and Lipid Changes: Urinary Albumin/Creatinine Ratio and ApoB/ApoA-1 Ratio [units: Correlation coefficient]	0.04760	0.25636	0.07766

51. Secondary Outcome Measure:

Measure Title	Relationship Between Renal Effects and Lipid Changes: eGFR and TC

Measure Description	Correlation of changes from baseline in eGFR with percent change from baseline in lipids and lipoprotein concentrations at Week 26.
Time Frame	26 weeks
Safety Issue?	No

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
Rosuvastatin	Rosuvastatin Treatments pooled
Atorvastatin	Atorvastatin Treatment
All Treatment	All Treatments pooled

Measured Values

	Rosuvastatin	Atorvastatin	All Treatment
Number of Participants Analyzed	211	91	302
Relationship Between Renal Effects and Lipid Changes: eGFR and TC [units: Correlation coefficient]	0.01586	-0.03124	0.00101

52. Secondary Outcome Measure:

Measure Title	Relationship Between Renal Effects and Lipid Changes: eGFR and TC
Measure Description	Correlation of changes from baseline in eGFR with percent change from baseline in lipids and lipoprotein concentrations at Week 52
Time Frame	52 Weeks
Safety Issue?	No

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
Rosuvastatin	Rosuvastatin Treatments pooled
Atorvastatin	Atorvastatin Treatment
All Treatment	All Treatments pooled

Measured Values

	Rosuvastatin	Atorvastatin	All Treatment
Number of Participants Analyzed	195	82	277
Relationship Between Renal Effects and Lipid Changes: eGFR and TC [units: Correlation coefficient]	-0.13489	-0.18105	-0.14690

53. Secondary Outcome Measure:

Measure Title	Relationship Between Renal Effects and Lipid Changes: eGFR and LDL-C
Measure Description	Correlation of changes from baseline in eGFR with percent change from baseline in lipids and lipoprotein concentrations at Week 26.
Time Frame	26 weeks
Safety Issue?	No

Analysis Population Description

[Not Specified]

Reporting Groups

	Description
Rosuvastatin	Rosuvastatin Treatments pooled
Atorvastatin	Atorvastatin Treatment
All Treatment	All Treatments pooled

Measured Values

	Rosuvastatin	Atorvastatin	All Treatment
Number of Participants Analyzed	209	90	299

	Rosuvastatin	Atorvastatin	All Treatment
Relationship Between Renal Effects and Lipid Changes: eGFR and LDL-C [units: Correlation coefficient]	0.03010	-0.00944	0.02609

54. Secondary Outcome Measure:

Measure Title	Relationship Between Renal Effects and Lipid Changes: eGFR and LDL-C
Measure Description	Correlation of changes from baseline in eGFR with percent change from baseline in lipids and lipoprotein concentrations at Week 52
Time Frame	52 Weeks
Safety Issue?	No

Analysis Population Description

[Not Specified]

Reporting Groups

	Description
Rosuvastatin	Rosuvastatin Treatments pooled
Atorvastatin	Atorvastatin Treatment
All Treatment	All Treatments pooled

Measured Values

	Rosuvastatin	Atorvastatin	All Treatment
Number of Participants Analyzed	195	81	276
Relationship Between Renal Effects and Lipid Changes: eGFR and LDL-C [units: Correlation coefficient]	-0.11072	-0.12835	-0.11378

55. Secondary Outcome Measure:

Measure Title	Relationship Between Renal Effects and Lipid Changes: eGFR and HDL-C

Measure Description	Correlation of changes from baseline in eGFR with percent change from baseline in lipids and lipoprotein concentrations at Week 26.
Time Frame	26 weeks
Safety Issue?	No

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
Rosuvastatin	Rosuvastatin Treatments pooled
Atorvastatin	Atorvastatin Treatment
All Treatment	All Treatments pooled

Measured Values

	Rosuvastatin	Atorvastatin	All Treatment
Number of Participants Analyzed	209	90	299
Relationship Between Renal Effects and Lipid Changes: eGFR and HDL-C [units: Correlation coefficient]	0.11373	0.01123	0.07576

56. Secondary Outcome Measure:

Measure Title	Relationship Between Renal Effects and Lipid Changes: eGFR and HDL-C
Measure Description	Correlation of changes from baseline in eGFR with percent change from baseline in lipids and lipoprotein concentrations at Week 52
Time Frame	52 Weeks
Safety Issue?	No

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
Rosuvastatin	Rosuvastatin Treatments pooled
Atorvastatin	Atorvastatin Treatment
All Treatment	All Treatments pooled

Measured Values

	Rosuvastatin	Atorvastatin	All Treatment
Number of Participants Analyzed	195	81	276
Relationship Between Renal Effects and Lipid Changes: eGFR and HDL-C [units: Correlation coefficient]	0.14457	-0.15546	0.08841

57. Secondary Outcome Measure:

Measure Title	Relationship Between Renal Effects and Lipid Changes: eGFR and nonHDL-C
Measure Description	Correlation of changes from baseline in eGFR with percent change from baseline in lipids and lipoprotein concentrations at Week 26.
Time Frame	26 weeks
Safety Issue?	No

Analysis Population Description

[Not Specified]

Reporting Groups

	Description
Rosuvastatin	Rosuvastatin Treatments pooled
Atorvastatin	Atorvastatin Treatment
All Treatment	All Treatments pooled

Measured Values

	Rosuvastatin	Atorvastatin	All Treatment
Number of Participants Analyzed	209	90	299

	Rosuvastatin	Atorvastatin	All Treatment
Relationship Between Renal Effects and Lipid Changes: eGFR and nonHDL-C [units: Correlation coefficient]	-0.01709	-0.05610	-0.02569

58. Secondary Outcome Measure:

Measure Title	Relationship Between Renal Effects and Lipid Changes: eGFR and nonHDL-C
Measure Description	Correlation of changes from baseline in eGFR with percent change from baseline in lipids and lipoprotein concentrations at Week 52
Time Frame	52 weeks
Safety Issue?	No

Analysis Population Description

[Not Specified]

Reporting Groups

	Description
Rosuvastatin	Rosuvastatin Treatments pooled
Atorvastatin	Atorvastatin Treatment
All Treatment	All Treatments pooled

Measured Values

	Rosuvastatin	Atorvastatin	All Treatment
Number of Participants Analyzed	195	81	276
Relationship Between Renal Effects and Lipid Changes: eGFR and nonHDL-C [units: Correlation coefficient]	-0.17729	-0.19501	-0.17911

59. Secondary Outcome Measure:

Measure Title	Relationship Between Renal Effects and Lipid Changes: eGFR and TG

Measure Description	Correlation of changes from baseline in eGFR with percent change from baseline in lipids and lipoprotein concentrations at Week 26.
Time Frame	26 weeks
Safety Issue?	No

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
Rosuvastatin	Rosuvastatin Treatments pooled
Atorvastatin	Atorvastatin Treatment
All Treatment	All Treatments pooled

Measured Values

	Rosuvastatin	Atorvastatin	All Treatment
Number of Participants Analyzed	211	91	302
Relationship Between Renal Effects and Lipid Changes: eGFR and TG [units: Correlation coefficient]	-0.10533	-0.00604	-0.09437

60. Secondary Outcome Measure:

Measure Title	Relationship Between Renal Effects and Lipid Changes: eGFR and TG
Measure Description	Correlation of changes from baseline in eGFR with percent change from baseline in lipids and lipoprotein concentrations at Week 52
Time Frame	52 weeks
Safety Issue?	No

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
Rosuvastatin	Rosuvastatin Treatments pooled
Atorvastatin	Atorvastatin Treatment
All Treatment	All Treatments pooled

Measured Values

	Rosuvastatin	Atorvastatin	All Treatment
Number of Participants Analyzed	195	82	277
Relationship Between Renal Effects and Lipid Changes: eGFR and TG [units: Correlation coefficient]	-0.24494	-0.07059	-0.15586

61. Secondary Outcome Measure:

Measure Title	Relationship Between Renal Effects and Lipid Changes: eGFR and TC/HDL-C Ratio
Measure Description	Correlation of changes from baseline in eGFR with percent change from baseline in lipids and lipoprotein concentrations at Week 26.
Time Frame	26 weeks
Safety Issue?	No

Analysis Population Description

[Not Specified]

Reporting Groups

	Description
Rosuvastatin	Rosuvastatin Treatments pooled
Atorvastatin	Atorvastatin Treatment
All Treatment	All Treatments pooled

Measured Values

	Rosuvastatin	Atorvastatin	All Treatment
Number of Participants Analyzed	209	90	299

	Rosuvastatin	Atorvastatin	All Treatment
Relationship Between Renal Effects and Lipid Changes: eGFR and TC/HDL-C Ratio [units: Correlation coefficient]	-0.05426	-0.01643	-0.04256

62. Secondary Outcome Measure:

Measure Title	Relationship Between Renal Effects and Lipid Changes: eGFR and TC/HDL-C Ratio
Measure Description	Correlation of changes from baseline in eGFR with percent change from baseline in lipids and lipoprotein concentrations at Week 52
Time Frame	52 weeks
Safety Issue?	No

Analysis Population Description

[Not Specified]

Reporting Groups

	Description
Rosuvastatin	Rosuvastatin Treatments pooled
Atorvastatin	Atorvastatin Treatment
All Treatment	All Treatments pooled

Measured Values

	Rosuvastatin	Atorvastatin	All Treatment
Number of Participants Analyzed	195	81	276
Relationship Between Renal Effects and Lipid Changes: eGFR and TC/HDL-C Ratio [units: Correlation coefficient]	-0.26268	-0.08593	-0.23226

63. Secondary Outcome Measure:

Measure Title	Relationship Between Renal Effects and Lipid Changes: eGFR and LDL-C/HDL-C Ratio

Measure Description	Correlation of changes from baseline in eGFR with percent change from baseline in lipids and lipoprotein concentrations at Week 26.
Time Frame	26 weeks
Safety Issue?	No

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
Rosuvastatin	Rosuvastatin Treatments pooled
Atorvastatin	Atorvastatin Treatment
All Treatment	All Treatments pooled

Measured Values

	Rosuvastatin	Atorvastatin	All Treatment
Number of Participants Analyzed	209	90	299
Relationship Between Renal Effects and Lipid Changes: eGFR and LDL-C/HDL-C Ratio [units: Correlation coefficient]	-0.01040	0.00241	0.00189

64. Secondary Outcome Measure:

Measure Title	Relationship Between Renal Effects and Lipid Changes: eGFR and LDL-C/HDL-C Ratio
Measure Description	Correlation of changes from baseline in eGFR with percent change from baseline in lipids and lipoprotein concentrations at Week 52
Time Frame	52 weeks
Safety Issue?	No

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
Rosuvastatin	Rosuvastatin Treatments pooled
Atorvastatin	Atorvastatin Treatment
All Treatment	All Treatments pooled

Measured Values

	Rosuvastatin	Atorvastatin	All Treatment
Number of Participants Analyzed	195	81	276
Relationship Between Renal Effects and Lipid Changes: eGFR and LDL-C/HDL-C Ratio [units: Correlation coefficient]	-0.19850	-0.06481	-0.17579

65. Secondary Outcome Measure:

Measure Title	Relationship Between Renal Effects and Lipid Changes: eGFR and nonHDL-C/HDL-C Ratio
Measure Description	Correlation of changes from baseline in eGFR with percent change from baseline in lipids and lipoprotein concentrations at Week 26.
Time Frame	26 weeks
Safety Issue?	No

Analysis Population Description

[Not Specified]

Reporting Groups

	Description
Rosuvastatin	Rosuvastatin Treatments pooled
Atorvastatin	Atorvastatin Treatment
All Treatment	All Treatments pooled

Measured Values

	Rosuvastatin	Atorvastatin	All Treatment
Number of Participants Analyzed	209	90	299

	Rosuvastatin	Atorvastatin	All Treatment
Relationship Between Renal Effects and Lipid Changes: eGFR and nonHDL-C/HDL-C Ratio [units: Correlation coefficient]	-0.06356	-0.04402	-0.05499

66. Secondary Outcome Measure:

Measure Title	Relationship Between Renal Effects and Lipid Changes: eGFR and nonHDL-C/HDL-C Ratio
Measure Description	Correlation of changes from baseline in eGFR with percent change from baseline in lipids and lipoprotein concentrations at Week 52
Time Frame	52 weeks
Safety Issue?	No

Analysis Population Description

[Not Specified]

Reporting Groups

	Description
Rosuvastatin	Rosuvastatin Treatments pooled
Atorvastatin	Atorvastatin Treatment
All Treatment	All Treatments pooled

Measured Values

	Rosuvastatin	Atorvastatin	All Treatment
Number of Participants Analyzed	195	81	276
Relationship Between Renal Effects and Lipid Changes: eGFR and nonHDL-C/HDL-C Ratio [units: Correlation coefficient]	-0.26802	-0.11804	-0.24204

67. Secondary Outcome Measure:

Measure Title	Relationship Between Renal Effects and Lipid Changes: eGFR and ApoA1

Measure Description	Correlation of changes from baseline in eGFR with percent change from baseline in lipids and lipoprotein concentrations at Week 26.
Time Frame	26 weeks
Safety Issue?	No

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
Rosuvastatin	Rosuvastatin Treatments pooled
Atorvastatin	Atorvastatin Treatment
All Treatment	All Treatments pooled

Measured Values

	Rosuvastatin	Atorvastatin	All Treatment
Number of Participants Analyzed	197	87	284
Relationship Between Renal Effects and Lipid Changes: eGFR and ApoA1 [units: Correlation coefficient]	0.08146	0.05333	0.05845

68. Secondary Outcome Measure:

Measure Title	Relationship Between Renal Effects and Lipid Changes: eGFR and ApoA1
Measure Description	Correlation of changes from baseline in eGFR with percent change from baseline in lipids and lipoprotein concentrations at Week 52
Time Frame	52 weeks
Safety Issue?	No

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
Rosuvastatin	Rosuvastatin Treatments pooled
Atorvastatin	Atorvastatin Treatment
All Treatment	All Treatments pooled

Measured Values

	Rosuvastatin	Atorvastatin	All Treatment
Number of Participants Analyzed	187	81	268
Relationship Between Renal Effects and Lipid Changes: eGFR and ApoA1 [units: Correlation coefficient]	0.17909	0.08090	0.12787

69. Secondary Outcome Measure:

Measure Title	Relationship Between Renal Effects and Lipid Changes: eGFR and ApoB
Measure Description	Correlation of changes from baseline in eGFR with percent change from baseline in lipids and lipoprotein concentrations at Week 26.
Time Frame	26 weeks
Safety Issue?	No

Analysis Population Description

[Not Specified]

Reporting Groups

	Description
Rosuvastatin	Rosuvastatin Treatments pooled
Atorvastatin	Atorvastatin Treatment
All Treatment	All Treatments pooled

Measured Values

	Rosuvastatin	Atorvastatin	All Treatment
Number of Participants Analyzed	197	87	284

	Rosuvastatin	Atorvastatin	All Treatment
Relationship Between Renal Effects and Lipid Changes: eGFR and ApoB [units: Correlation coefficient]	-0.01427	0.08821	0.00737

70. Secondary Outcome Measure:

Measure Title	Relationship Between Renal Effects and Lipid Changes: eGFR and ApoB
Measure Description	Correlation of changes from baseline in eGFR with percent change from baseline in lipids and lipoprotein concentrations at Week 52
Time Frame	52 weeks
Safety Issue?	No

Analysis Population Description

[Not Specified]

Reporting Groups

	Description
Rosuvastatin	Rosuvastatin Treatments pooled
Atorvastatin	Atorvastatin Treatment
All Treatment	All Treatments pooled

Measured Values

	Rosuvastatin	Atorvastatin	All Treatment
Number of Participants Analyzed	187	81	268
Relationship Between Renal Effects and Lipid Changes: eGFR and ApoB [units: Correlation coefficient]	-0.15146	0.04886	-0.12168

71. Secondary Outcome Measure:

Measure Title	Relationship Between Renal Effects and Lipid Changes: eGFR and ApoB/ApoA-1 Ratio

Measure Description	Correlation of changes from baseline in eGFR with percent change from baseline in lipids and lipoprotein concentrations at Week 26.
Time Frame	26 weeks
Safety Issue?	No

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
Rosuvastatin	Rosuvastatin Treatments pooled
Atorvastatin	Atorvastatin Treatment
All Treatment	All Treatments pooled

Measured Values

	Rosuvastatin	Atorvastatin	All Treatment
Number of Participants Analyzed	197	87	284
Relationship Between Renal Effects and Lipid Changes: eGFR and ApoB/ApoA-1 Ratio [units: Correlation coefficient]	-0.04088	0.06598	-0.01652

72. Secondary Outcome Measure:

Measure Title	Relationship Between Renal Effects and Lipid Changes: eGFR and ApoB/ApoA-1 Ratio
Measure Description	Correlation of changes from baseline in eGFR with percent change from baseline in lipids and lipoprotein concentrations at Week 52
Time Frame	52 weeks
Safety Issue?	No

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
Rosuvastatin	Rosuvastatin Treatments pooled
Atorvastatin	Atorvastatin Treatment
All Treatment	All Treatments pooled

Measured Values

	Rosuvastatin	Atorvastatin	All Treatment
Number of Participants Analyzed	187	81	268
Relationship Between Renal Effects and Lipid Changes: eGFR and ApoB/ApoA-1 Ratio [units: Correlation coefficient]	-0.26146	0.05248	-0.22109

Reported Adverse Events

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

Reporting Groups

	Description
Rosuvastatin 10mg	
Rosuvastatin 40mg	
Atorvastatin 80mg	

Serious Adverse Events

	Rosuvastatin 10mg	Rosuvastatin 40mg	Atorvastatin 80mg
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	18/116 (15.52%)	20/123 (16.26%)	21/110 (19.09%)
Cardiac disorders			
Acute Myocardial Infarction [A] †	1/116 (0.86%)	0/123 (0%)	1/110 (0.91%)

	Rosuvastatin 10mg	Rosuvastatin 40mg	Atorvastatin 80mg
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Angina Pectoris [A] †	2/116 (1.72%)	1/123 (0.81%)	2/110 (1.82%)
Angina Unstable [A] †	0/116 (0%)	0/123 (0%)	1/110 (0.91%)
Atrial Fibrillation [A] †	0/116 (0%)	0/123 (0%)	1/110 (0.91%)
Cardiac Failure [A] †	3/116 (2.59%)	1/123 (0.81%)	1/110 (0.91%)
Coronary Artery Stenosis [A] †	0/116 (0%)	1/123 (0.81%)	0/110 (0%)
Left Ventricular Failure [A] †	0/116 (0%)	1/123 (0.81%)	0/110 (0%)
Myocardial Ischaemia [A] †	0/116 (0%)	0/123 (0%)	1/110 (0.91%)
Eye disorders			
Cataract [A] †	0/116 (0%)	1/123 (0.81%)	0/110 (0%)
Diabetic Eye Disease [A] †	1/116 (0.86%)	0/123 (0%)	0/110 (0%)
Diabetic Retinopathy [A] †	0/116 (0%)	1/123 (0.81%)	0/110 (0%)
Vitreous Haemorrhage [A] †	1/116 (0.86%)	0/123 (0%)	0/110 (0%)
Gastrointestinal disorders			
Abdominal Pain [A] †	0/116 (0%)	1/123 (0.81%)	0/110 (0%)
Gastric Ulcer [A] †	0/116 (0%)	0/123 (0%)	1/110 (0.91%)
Gastrointestinal Haemorrhage [A] †	0/116 (0%)	1/123 (0.81%)	0/110 (0%)
Gastrooesophageal Reflux Disease [A] †	1/116 (0.86%)	0/123 (0%)	0/110 (0%)
Ileus Paralytic [A] †	0/116 (0%)	0/123 (0%)	1/110 (0.91%)
Intestinal Polyp [A] †	1/116 (0.86%)	0/123 (0%)	0/110 (0%)
General disorders			
Chest Pain [A] †	0/116 (0%)	1/123 (0.81%)	0/110 (0%)
Death [A] †	1/116 (0.86%)	1/123 (0.81%)	0/110 (0%)

	Rosuvastatin 10mg	Rosuvastatin 40mg	Atorvastatin 80mg
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Oedema Peripheral [A] †	2/116 (1.72%)	0/123 (0%)	0/110 (0%)
Pyrexia [A] †	0/116 (0%)	1/123 (0.81%)	0/110 (0%)
Soft Tissue Inflammation [A] †	1/116 (0.86%)	0/123 (0%)	0/110 (0%)
Sudden Death [A] †	1/116 (0.86%)	0/123 (0%)	0/110 (0%)
Hepatobiliary disorders			
Cholecystitis Acute [A] †	1/116 (0.86%)	0/123 (0%)	0/110 (0%)
Infections and infestations			
Abdominal Infection [A] †	0/116 (0%)	1/123 (0.81%)	0/110 (0%)
Abscess Limb [A] †	0/116 (0%)	1/123 (0.81%)	0/110 (0%)
Cellulitis [A] †	0/116 (0%)	0/123 (0%)	1/110 (0.91%)
Gangrene [A] †	0/116 (0%)	1/123 (0.81%)	1/110 (0.91%)
Influenza [A] †	0/116 (0%)	1/123 (0.81%)	0/110 (0%)
Osteomyelitis [A] †	0/116 (0%)	0/123 (0%)	1/110 (0.91%)
Pneumonia [A] †	0/116 (0%)	0/123 (0%)	1/110 (0.91%)
Pyelonephritis Chronic [A] †	1/116 (0.86%)	0/123 (0%)	0/110 (0%)
Skin Infection [A] †	0/116 (0%)	0/123 (0%)	1/110 (0.91%)
Injury, poisoning and procedural complications			
Hip Fracture [A] †	0/116 (0%)	0/123 (0%)	1/110 (0.91%)
Vascular Graft Occlusion [A] †	0/116 (0%)	0/123 (0%)	1/110 (0.91%)
Metabolism and nutrition disorders			
Diabetes Mellitus Inadequate Control [A] †	0/116 (0%)	0/123 (0%)	2/110 (1.82%)
Diabetic Ketoacidosis [A] †	1/116 (0.86%)	1/123 (0.81%)	0/110 (0%)
Hyperglycaemia [A] †	0/116 (0%)	1/123 (0.81%)	1/110 (0.91%)

	Rosuvastatin 10mg	Rosuvastatin 40mg	Atorvastatin 80mg
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Musculoskeletal and connective tissue disorders			
Osteitis [A] †	0/116 (0%)	1/123 (0.81%)	0/110 (0%)
Pseudarthrosis [A] †	0/116 (0%)	1/123 (0.81%)	0/110 (0%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Metastases To Central Nervous System [A] †	0/116 (0%)	0/123 (0%)	1/110 (0.91%)
Nervous system disorders			
Aphasia [A] †	0/116 (0%)	0/123 (0%)	1/110 (0.91%)
Cerebrovascular Accident [A] †	0/116 (0%)	1/123 (0.81%)	0/110 (0%)
Headache [A] †	1/116 (0.86%)	0/123 (0%)	0/110 (0%)
Presyncope [A] †	0/116 (0%)	0/123 (0%)	1/110 (0.91%)
Syncope [A] †	0/116 (0%)	1/123 (0.81%)	0/110 (0%)
Transient Ischaemic Attack [A] †	0/116 (0%)	0/123 (0%)	1/110 (0.91%)
Pregnancy, puerperium and perinatal conditions			
Abortion Spontaneous [A] †	0/116 (0%)	0/123 (0%)	2/110 (1.82%)
Psychiatric disorders			
Factitious Disorder [A] †	0/116 (0%)	0/123 (0%)	1/110 (0.91%)
Renal and urinary disorders			
Diabetic Nephropathy [A] †	0/116 (0%)	0/123 (0%)	1/110 (0.91%)
Haematuria [A] †	1/116 (0.86%)	0/123 (0%)	0/110 (0%)
Nephrolithiasis [A] †	0/116 (0%)	1/123 (0.81%)	0/110 (0%)
Renal Failure [A] †	0/116 (0%)	1/123 (0.81%)	0/110 (0%)
Renal Failure Acute [A] †	0/116 (0%)	2/123 (1.63%)	0/110 (0%)
Respiratory, thoracic and mediastinal disorders			

	Rosuvastatin 10mg	Rosuvastatin 40mg	Atorvastatin 80mg
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Dyspnoea [A] †	1/116 (0.86%)	1/123 (0.81%)	0/110 (0%)
Hypoxia [A] †	1/116 (0.86%)	0/123 (0%)	0/110 (0%)
Pickwickian Syndrome [A] †	1/116 (0.86%)	0/123 (0%)	0/110 (0%)
Respiratory Failure [A] †	1/116 (0.86%)	0/123 (0%)	0/110 (0%)
Sleep Apnoea Syndrome [A] †	1/116 (0.86%)	0/123 (0%)	0/110 (0%)
Vascular disorders			
Femoral Arterial Stenosis [A] †	0/116 (0%)	0/123 (0%)	1/110 (0.91%)
Hypotension [A] †	0/116 (0%)	0/123 (0%)	1/110 (0.91%)
Poor Peripheral Circulation [A] †	0/116 (0%)	0/123 (0%)	1/110 (0.91%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA 12.0

Other Adverse Events

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

	Rosuvastatin 10mg	Rosuvastatin 40mg	Atorvastatin 80mg
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	15/116 (12.93%)	25/123 (20.33%)	12/110 (10.91%)
General disorders			
Oedema Peripheral [A] †	9/116 (7.76%)	5/123 (4.07%)	3/110 (2.73%)
Infections and infestations			
Influenza [A] †	3/116 (2.59%)	7/123 (5.69%)	0/110 (0%)
Musculoskeletal and connective tissue disorders			
Myalgia [A] †	3/116 (2.59%)	6/123 (4.88%)	7/110 (6.36%)
Vascular disorders			
Hypertension [A] †	2/116 (1.72%)	8/123 (6.5%)	2/110 (1.82%)

† Indicates events were collected by systematic assessment.

A Term from vocabulary, MedDRA 12.0

Limitations and Caveats

[Not specified]

More Information

Certain Agreements:

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

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 from the time submitted to the sponsor for review. The sponsor cannot require changes to the communication and cannot extend the embargo.

Results Point of Contact:

Name/Official Title: Gerard Lynch
Organization: AstraZeneca
Phone:
Email: aztrial_results_posting@astrazeneca.com