ClinicalTrials.gov Protocol and Results Registration System (PRS) Receipt
Release Date: 07/11/2012

ClinicalTrials.gov ID: NCT00620542

Study Identification

Unique Protocol ID:	D356IC00001
Brief Title:	CRESTOR Athero Imaging Head to Head IVUS Study (SATURN)
Official Title:	Study of Coronary Atheroma by Intravascular Ultrasound: Effect of Rosuvastatin Versus Atorvastatin (SATURN)
Secondary IDs:	2007-004000-13

Study Status

Record Verification:	July 2012
Overall Status:	Completed
Study Start:	January 2008
Primary Completion:	June 2011 [Actual]
Study Completion:	June 2011 [Actual]

Sponsor/Collaborators

Sponsor:	AstraZeneca
Responsible Party:	Sponsor
Collaborators:	The Cleveland Clinic

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: 640 Has Expanded Access? No
Review Board:	Approval Status: Board Name: Board Affiliation: Phone: Email:
Data Monitoring?:	
Plan to Share Data?:	
Oversight Authorities:	Australia: Department of Health and Ageing Therapeutic Goods Administration Argentina: Administracion Nacional de Medicamentos, Alimentos y Tecnologia Medica Belgium: Ministry of Social Affairs, Public Health and the Environment Canada: Health Canada France: Afssaps - Agence française de sécurité sanitaire des produits de santé (Saint-Denis) Italy: Ministry of Health Mexico: Ministry of Health Netherlands: Medicines Evaluation Board (MEB) Poland: Office for Registration of Medicinal Products, Medical Devices and Biocidal Products Spain: Spanish Agency of Medicines United States: Food and Drug Administration

Study Description

Brief Summary:	A 104-week, randomized, double-blind, parallel group, multi-center Phase IIIb study comparing the effects of treatment with rosuvastatin 40 mg or atorvastatin 80 mg on atherosclerotic disease burden as measured by intravascular ultrasound in patients with coronary artery disease.
Detailed Description:	

Conditions

Conditions:	Coronary Atherosclerosis
Keywords:	Coronary artery disease

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 3
Intervention Model:	Parallel Assignment
Number of Arms:	4
Masking:	Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor)
Allocation:	Randomized
Endpoint Classification:	Efficacy Study
Enrollment:	2333 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: Rosuvastatin 20 mg Rosuvastatin 20 mg distributed in 2-week run-in period	Drug: Rosuvastatin capsule, oral, once daily Other Names: • Crestor
Active Comparator: Atorvastatin 40 mg Atorvastatin 40 mg distributed in 2-week run-in period	Drug: Atorvastatin capsule, oral, one daily Other Names: • Lipitor
Experimental: Rosuvastatin 40 mg Rosuvastatin 40 mg distributed in core 2-year study	Drug: Rosuvastatin capsule, oral, once daily Other Names: • Crestor
Active Comparator: Atorvastatin 80 mg Atorvastatin 80 mg distributed in core 2-year study	Drug: Atorvastatin capsule, oral, one daily Other Names: • Lipitor

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age: 18 Years

Maximum Age: 75 Years

Gender: Both

Accepts Healthy Volunteers?: No

Criteria: Inclusion Criteria:

- Clinical indication for coronary angiography
- Angiographic evidence of Coronary Artery Disease (CAD), as defined by at least 1 lesion in a native coronary artery that has >20% reduction in lumen diameter by visual estimation
- Left main coronary artery must have <=50% reduction in lumen diameter by visual estimation
- LDL-C >100 mg/dL (2.6 mmol/L) for patients with no statin therapy in the past 4 weeks; LDL-C >80mg/dL (2.08mmol/L) for patients on therapy in the past 4 weeks

Exclusion Criteria:

- Use of certain lipid-lowering medication for more than 3 months within the previous 12 months. Longer periods of treatment are not permitted because of the potential effects of such therapy on coronary atherosclerosis.
- Patients who have symptoms consistent with moderate or greater severity of Congestive Heart Failure (CHF).
- Clinically significant heart disease which, in the opinion of the Principal Investigator (or designee), is likely to require coronary bypass surgery, cardiac transplantation, surgical repair and/or replacement during the course of the study

Contacts/Locations

Study Officials: Stephen J Nicholls, MBBS, PhD
Study Principal Investigator
Cleveland Clinic Foundation, Cardiovascular Medicine

Locations: Argentina
Research Site
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Research Site
Cap. Fed., Buenos Aires, Argentina

Research Site
Ciudad de Buenos Aires, Buenos Aires, Argentina

Research Site
Cordoba, Cordoba, Argentina

Research Site
Corrientes, Corrientes, Argentina

Research Site
Rosario, Santa Fe-argentina, Argentina

Australia, South Australia
Research Site
Adelaide, South Australia, Australia

Australia, Queensland
Research Site
Chermside, Queensland, Australia

Australia, New South Wales
Research Site
Liverpool, New South Wales, Australia

Research Site
New Lambton Heights, New South Wales, Australia

Australia, Western Australia
Research Site
Perth, Western Australia, Australia

Belgium
Research Site
Aalst, Belgium, Belgium

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Brugge, Belgium, Belgium

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Brussels, Belgium, Belgium

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Charleroi, Belgium, Belgium

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Genk, Belgium, Belgium

Research Site
Leuven, Belgium, Belgium

Brazil
Research Site

Cariacica, ES, Brazil

Research Site
Cuiaba, MT, Brazil

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Curitiba, PR, Brazil

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Goiania, GO, Brazil

Research Site
Ribeirao Preto, SP, Brazil

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Sao Paulo, SP, Brazil

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Uberlandia, MG, Brazil

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Vitoria, ES, Brazil

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Chicoutimi, Quebec, Canada

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Edmonton, Alberta, Canada

Canada, Nova Scotia
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Hamilton, Ontario, Canada

Canada, Quebec
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London, Ontario, Canada

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Canada, Manitoba
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Winnipeg, Manitoba, Canada

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Bron, France

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Research Site

Wormleysburg, Pennsylvania, United States

References

Citations:

Links:

Study Data/Documents:

Study Results

Participant Flow

Recruitment Details	2333 Coronary Artery Disease (CAD) patients with clinical indication for coronary angiography were randomized to Part A, the 2-week run-in period. Of these, 1578 patients were treated and 1385 completed Part A. The 1385 patients completing Part A were then randomized to Part B the core study period of 104 weeks of treatment.
Pre-Assignment Details	Angiography was performed to determine if patients were qualified to continue in the study based on protocol-specified angiographic criteria. Patients who satisfied all inclusion and exclusion criteria had an Intravascular Ultrasound (IVUS) performed within 2 weeks of the qualifying angiography.

Reporting Groups

	Description
Rosuvastatin 20 mg	2 week run-in period
Atorvastatin 40 mg	2 week run-in period
Rosuvastatin 40 mg	2 year core study
Atorvastatin 80 mg	2 year core study

Part A (Run-in - 2 Weeks)

	Rosuvastatin 20 mg	Atorvastatin 40 mg	Rosuvastatin 40 mg	Atorvastatin 80 mg
Started	1167 [1]	1166 [2]	0	0
Received Treatment	783	795	0	0
Completed	695	690	0	0

	Rosuvastatin 20 mg	Atorvastatin 40 mg	Rosuvastatin 40 mg	Atorvastatin 80 mg
Not Completed	472	476	0	0
Adverse Event	12	15	0	0
Protocol Violation	406	409	0	0
Withdrawal by Subject	43	40	0	0
Lost to Follow-up	7	6	0	0
Protocol Violation	0	1	0	0
Safety reasons	0	1	0	0
IVUS not available	4	4	0	0

[1] Of 1167 randomized, N=783 received treatment.
[2] Of 1166 randomized, N=795 received treatment.

Part B (2 Year Core Study)

	Rosuvastatin 20 mg	Atorvastatin 40 mg	Rosuvastatin 40 mg	Atorvastatin 80 mg
Started	0	0	694 [1]	691 [2]
Received Treatment	0	0	691	689
Intent-to-treat Population	0	0	520 [3]	519 [3]
Completed	0	0	546	547
Not Completed	0	0	148	144
Adverse Event	0	0	46	49
Protocol Violation	0	0	3	5
Withdrawal by Subject	0	0	55	54
Lost to Follow-up	0	0	20	9
Protocol Violation	0	0	13	16
Safety reasons	0	0	2	3
Study specific discontinuation criteris	0	0	6	6
IVUS not available	0	0	3	2

[1] Of 694 patients randomized, N=691 received treatment.
[2] Of 691 patients randomized, N=689 received treatment.

[3] Patients who received treatment and had a baseline and end of study (Week 104) IVUS

Baseline Characteristics

Reporting Groups

	Description
Rosuvastatin 40 mg	2 years
Atorvastatin 80 mg	2 years

Baseline Measures

	Rosuvastatin 40 mg	Atorvastatin 80 mg	Total
Number of Participants	520	519	1039
Age, Categorical [units: Participants]			
<=18 years	0	0	0
Between 18 and 65 years	402	395	797
>=65 years	118	124	242
Age, Continuous Age (yrs) at Week 0 [units: years] Mean (Standard Deviation)	57.4 (8.60)	57.9 (8.50)	57.6 (8.55)
Gender, Male/Female [units: Participants]			
Female	141	133	274
Male	379	386	765

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Change From Baseline to End of Study (Week 104) in Percent Atheroma Volume (PAV)
Measure Description	Change in PAV computed as PAV(Week 104)-PAV(baseline) where PAV is calculated as: [sum(EEMcsa-LUMENcsa)/sum EEMcsa]*100 where EEMcsa is the cross-sectional area of the external elastic membrane and LUMENcsa is the cross-sectional area of the lumen, as measured by intravascular ultrasound IVUS of a coronary artery in patients with CAD.

Time Frame	End of study (Week 104)
Safety Issue?	No

Analysis Population Description

Intent-to-Treat population (patients received at least one dose of study drug and had pre-study and post-study IVUS).

Reporting Groups

	Description
Rosuvastatin 40 mg	Part B: Rosuvastatin 40 mg for core study - 2 years
Atorvastatin 80 mg	Part B: Atorvastatin 80 mg for core study - 2 years

Measured Values

	Rosuvastatin 40 mg	Atorvastatin 80 mg
Number of Participants Analyzed	520	519
Change From Baseline to End of Study (Week 104) in Percent Atheroma Volume (PAV) [units: Percent change] Median (95% Confidence Interval)	-1.22 (-1.52 to -0.90)	-0.99 (-1.19 to -0.63)

2. Secondary Outcome Measure:

Measure Title	Numbers of Patients Showing Regression in PAV
Measure Description	Regression defined as a change from baseline in PAV < 0
Time Frame	End of study (Week 104)
Safety Issue?	No

Analysis Population Description

Intent-to-Treat population (patients received at least one dose of study drug and had pre-study and post-study IVUS).

Reporting Groups

	Description
Rosuvastatin 40 mg	Part B: Rosuvastatin 40 mg for core study - 2 years
Atorvastatin 80 mg	Part B: Atorvastatin 80 mg for core study - 2 years

Measured Values

	Rosuvastatin 40 mg	Atorvastatin 80 mg
Number of Participants Analyzed	520	519
Numbers of Patients Showing Regression in PAV [units: Participants]	356	328

3. Secondary Outcome Measure:

Measure Title	Change From Baseline to End of Study (Week 104) in Total Atheroma Volume (TAV)
Measure Description	Change in TAV, as measured by IVUS, computed as TAV(Week 104)-TAV(baseline) where TAV is the sum(EEMcsa-LUMENcsa)/n. n is the number of cross-sections measured. TAV for each patient is calculated as the average area of atheroma per cross-section multiplied by the median number of cross-sections measured for all patients in the analysis population.
Time Frame	End of study (Week 104)
Safety Issue?	No

Analysis Population Description

Intent-to-Treat population (patients received at least one dose of study drug and had pre-study and post-study IVUS).

Reporting Groups

	Description
Rosuvastatin 40 mg	Part B: Rosuvastatin 40 mg for core study - 2 years
Atorvastatin 80 mg	Part B: Atorvastatin 80 mg for core study - 2 years

Measured Values

	Rosuvastatin 40 mg	Atorvastatin 80 mg
Number of Participants Analyzed	520	519
Change From Baseline to End of Study (Week 104) in Total Atheroma Volume (TAV) [units: mm^3] Median (95% Confidence Interval)	-6.39 (-7.52 to -5.12)	-4.42 (-5.98 to -3.26)

4. Secondary Outcome Measure:

Measure Title	Numbers of Patients Showing Regression in TAV
Measure Description	Regression defined as a change from baseline in TAV < 0
Time Frame	End of study (Week 104)
Safety Issue?	No

Analysis Population Description

Intent-to-Treat population (patients received at least one dose of study drug and had pre-study and post-study IVUS).

Reporting Groups

	Description
Rosuvastatin 40 mg	Part B: Rosuvastatin 40 mg for core study - 2 years
Atorvastatin 80 mg	Part B: Atorvastatin 80 mg for core study - 2 years

Measured Values

	Rosuvastatin 40 mg	Atorvastatin 80 mg
Number of Participants Analyzed	520	519
Numbers of Patients Showing Regression in TAV [units: Participants]	371	336

5. Secondary Outcome Measure:

Measure Title	Total Cholesterol Blood Level
Measure Description	Time-weighted average is calculated as the lipid value times the number of days since last lipid assessment, summed for all and divided by the number of days from Part B randomization to date of the last lipid evaluation.
Time Frame	104 weeks
Safety Issue?	No

Analysis Population Description

Intent-to-Treat population (patients received at least one dose of study drug and had pre-study and post-study IVUS).

Reporting Groups

	Description
Rosuvastatin 40 mg	Part B: Rosuvastatin 40 mg for core study - 2 years

	Description
Atorvastatin 80 mg	Part B: Atorvastatin 80 mg for core study - 2 years

Measured Values

	Rosuvastatin 40 mg	Atorvastatin 80 mg
Number of Participants Analyzed	519	519
Total Cholesterol Blood Level [units: mg/dL] Least Squares Mean (Standard Error)	139.38 (1.24)	144.05 (1.23)

6. Secondary Outcome Measure:

Measure Title	LDL-C Blood Level
Measure Description	Time-weighted average is calculated as the lipid value times the number of days since last lipid assessment, summed for all and divided by the number of days from Part B randomization to date of the last lipid evaluation.
Time Frame	104 weeks
Safety Issue?	No

Analysis Population Description

Intent-to-Treat population (patients received at least one dose of study drug and had pre-study and post-study IVUS).

Reporting Groups

	Description
Rosuvastatin 40 mg	Part B: Rosuvastatin 40 mg for core study - 2 years
Atorvastatin 80 mg	Part B: Atorvastatin 80 mg for core study - 2 years

Measured Values

	Rosuvastatin 40 mg	Atorvastatin 80 mg
Number of Participants Analyzed	519	519
LDL-C Blood Level [units: mg/dL] Least Squares Mean (Standard Error)	62.64 (1.00)	70.18 (0.99)

7. Secondary Outcome Measure:

Measure Title	HDL-C Blood Level
Measure Description	Time-weighted average is calculated as the lipid value times the number of days since last lipid assessment, summed for all and divided by the number of days from Part B randomization to date of the last lipid evaluation.
Time Frame	104 weeks
Safety Issue?	No

Analysis Population Description

Intent-to-Treat population (patients received at least one dose of study drug and had pre-study and post-study IVUS).

Reporting Groups

	Description
Rosuvastatin 40 mg	Part B: Rosuvastatin 40 mg for core study - 2 years
Atorvastatin 80 mg	Part B: Atorvastatin 80 mg for core study - 2 years

Measured Values

	Rosuvastatin 40 mg	Atorvastatin 80 mg
Number of Participants Analyzed	519	519
HDL-C Blood Level [units: mg/dL] Least Squares Mean (Standard Error)	50.43 (0.54)	48.64 (0.53)

8. Secondary Outcome Measure:

Measure Title	Triglycerides Blood Level
Measure Description	Time-weighted average is calculated as the lipid value times the number of days since last lipid assessment, summed for all and divided by the number of days from Part B randomization to date of the last lipid evaluation.
Time Frame	104 weeks
Safety Issue?	No

Analysis Population Description

Intent-to-Treat population (patients received at least one dose of study drug and had pre-study and post-study IVUS).

Reporting Groups

	Description
Rosuvastatin 40 mg	Part B: Rosuvastatin 40 mg for core study - 2 years
Atorvastatin 80 mg	Part B: Atorvastatin 80 mg for core study - 2 years

Measured Values

	Rosuvastatin 40 mg	Atorvastatin 80 mg
Number of Participants Analyzed	519	519
Triglycerides Blood Level [units: mg/dL] Least Squares Mean (Standard Error)	132.50 (2.44)	126.58 (2.43)

9. Secondary Outcome Measure:

Measure Title	Non-HDL-C Blood Level
Measure Description	Time-weighted average is calculated as the lipid value times the number of days since last lipid assessment, summed for all and divided by the number of days from Part B randomization to date of the last lipid evaluation.
Time Frame	104 weeks
Safety Issue?	No

Analysis Population Description

Intent-to-Treat population (patients received at least one dose of study drug and had pre-study and post-study IVUS).

Reporting Groups

	Description
Rosuvastatin 40 mg	Part B: Rosuvastatin 40 mg for core study - 2 years
Atorvastatin 80 mg	Part B: Atorvastatin 80 mg for core study - 2 years

Measured Values

	Rosuvastatin 40 mg	Atorvastatin 80 mg
Number of Participants Analyzed	519	519
Non-HDL-C Blood Level [units: mg/dL] Least Squares Mean (Standard Error)	88.95 (1.15)	95.41 (1.14)

10. Secondary Outcome Measure:

Measure Title	LDL-C/HDL-C Blood Level
Measure Description	Time-weighted average is calculated as the lipid value times the number of days since last lipid assessment, summed for all and divided by the number of days from Part B randomization to date of the last lipid evaluation.
Time Frame	104 weeks
Safety Issue?	No

Analysis Population Description

Intent-to-Treat population (patients received at least one dose of study drug and had pre-study and post-study IVUS).

Reporting Groups

	Description
Rosuvastatin 40 mg	Part B: Rosuvastatin 40 mg for core study - 2 years
Atorvastatin 80 mg	Part B: Atorvastatin 80 mg for core study - 2 years

Measured Values

	Rosuvastatin 40 mg	Atorvastatin 80 mg
Number of Participants Analyzed	519	519
LDL-C/HDL-C Blood Level [units: Ratio] Least Squares Mean (Standard Error)	1.30 (0.02)	1.50 (0.02)

11. Secondary Outcome Measure:

Measure Title	Total Cholesterol/HDL-C Blood Level
Measure Description	Time-weighted average is calculated as the lipid value times the number of days since last lipid assessment, summed for all and divided by the number of days from Part B randomization to date of the last lipid evaluation.
Time Frame	104 weeks
Safety Issue?	No

Analysis Population Description

Intent-to-Treat population (patients received at least one dose of study drug and had pre-study and post-study IVUS).

Reporting Groups

	Description
Rosuvastatin 40 mg	Part B: Rosuvastatin 40 mg for core study - 2 years
Atorvastatin 80 mg	Part B: Atorvastatin 80 mg for core study - 2 years

Measured Values

	Rosuvastatin 40 mg	Atorvastatin 80 mg
Number of Participants Analyzed	519	519
Total Cholesterol/HDL-C Blood Level [units: Ratio] Least Squares Mean (Standard Error)	2.88 (0.03)	3.08 (0.03)

12. Secondary Outcome Measure:

Measure Title	Non-HDL-C/HDL-C Blood Level
Measure Description	Time-weighted average is calculated as the lipid value times the number of days since last lipid assessment, summed for all and divided by the number of days from Part B randomization to date of the last lipid evaluation.
Time Frame	104 weeks
Safety Issue?	No

Analysis Population Description

Intent-to-Treat population (patients received at least one dose of study drug and had pre-study and post-study IVUS).

Reporting Groups

	Description
Rosuvastatin 40 mg	Part B: Rosuvastatin 40 mg for core study - 2 years
Atorvastatin 80 mg	Part B: Atorvastatin 80 mg for core study - 2 years

Measured Values

	Rosuvastatin 40 mg	Atorvastatin 80 mg
Number of Participants Analyzed	519	519
Non-HDL-C/HDL-C Blood Level [units: Ratio] Least Squares Mean (Standard Error)	1.88 (0.03)	2.08 (0.03)

13. Secondary Outcome Measure:

Measure Title	Apolipoprotein B Blood Level
Measure Description	Time-weighted average is calculated as the lipid value times the number of days since last lipid assessment, summed for all and divided by the number of days from Part B randomization to date of the last lipid evaluation.
Time Frame	104 weeks
Safety Issue?	No

Analysis Population Description

Intent-to-Treat population (patients received at least one dose of study drug and had pre-study and post-study IVUS).

Reporting Groups

	Description
Rosuvastatin 40 mg	Part B: Rosuvastatin 40 mg for core study - 2 years
Atorvastatin 80 mg	Part B: Atorvastatin 80 mg for core study - 2 years

Measured Values

	Rosuvastatin 40 mg	Atorvastatin 80 mg
Number of Participants Analyzed	518	519
Apolipoprotein B Blood Level [units: mg/dL] Least Squares Mean (Standard Error)	72.55 (0.85)	75.12 (0.85)

14. Secondary Outcome Measure:

Measure Title	Apolipoprotein A-1 Blood Level
Measure Description	Time-weighted average is calculated as the lipid value times the number of days since last lipid assessment, summed for all and divided by the number of days from Part B randomization to date of the last lipid evaluation.
Time Frame	104 weeks
Safety Issue?	No

Analysis Population Description

Intent-to-Treat population (patients received at least one dose of study drug and had pre-study and post-study IVUS).

Reporting Groups

	Description
Rosuvastatin 40 mg	Part B: Rosuvastatin 40 mg for core study - 2 years
Atorvastatin 80 mg	Part B: Atorvastatin 80 mg for core study - 2 years

Measured Values

	Rosuvastatin 40 mg	Atorvastatin 80 mg
Number of Participants Analyzed	518	519
Apolipoprotein A-1 Blood Level [units: mg/dL] Least Squares Mean (Standard Error)	146.81 (1.03)	137.68 (1.02)

15. Secondary Outcome Measure:

Measure Title	Apoliprotein B/Apolipoprotein A-1 Blood Level
Measure Description	Time-weighted average is calculated as the lipid value times the number of days since last lipid assessment, summed for all and divided by the number of days from Part B randomization to date of the last lipid evaluation.
Time Frame	104 weeks
Safety Issue?	No

Analysis Population Description

Intent-to-Treat population (patients received at least one dose of study drug and had pre-study and post-study IVUS).

Reporting Groups

	Description
Rosuvastatin 40 mg	Part B: Rosuvastatin 40 mg for core study - 2 years
Atorvastatin 80 mg	Part B: Atorvastatin 80 mg for core study - 2 years

Measured Values

	Rosuvastatin 40 mg	Atorvastatin 80 mg
Number of Participants Analyzed	518	519
Apoliprotein B/Apolipoprotein A-1 Blood Level [units: Ratio] Least Squares Mean (Standard Error)	0.51 (0.01)	0.56 (0.01)

16. Secondary Outcome Measure:

Measure Title	VLDL-C During the 104 Week Treatment Period
Measure Description	Time-weighted average is calculated as the lipid value times the number of days since last lipid assessment, summed for all and divided by the number of days from Part B randomization to date of the last lipid evaluation.
Time Frame	104 weeks
Safety Issue?	No

Analysis Population Description

Intent-to-Treat population (patients received at least one dose of study drug and had pre-study and post-study IVUS).

Reporting Groups

	Description
Rosuvastatin 40 mg	Part B: Rosuvastatin 40 mg for core study - 2 years
Atorvastatin 80 mg	Part B: Atorvastatin 80 mg for core study - 2 years

Measured Values

	Rosuvastatin 40 mg	Atorvastatin 80 mg
Number of Participants Analyzed	519	519
VLDL-C During the 104 Week Treatment Period [units: mg/dL] Least Squares Mean (Standard Error)	26.05 (0.45)	25.03 (0.44)

Reported Adverse Events

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

Reporting Groups

	Description
Rosuvastatin 20 mg	2 week run-in period

	Description
Atorvastatin 40 mg	2 week run-in period
Rosuvastatin 40 mg	2 year core study
Atorvastatin 80 mg	2 year core study

Serious Adverse Events

	Rosuvastatin 20 mg	Atorvastatin 40 mg	Rosuvastatin 40 mg	Atorvastatin 80 mg
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	21/783 (2.68%)	25/795 (3.14%)	194/691 (28.08%)	168/689 (24.38%)
Blood and lymphatic system disorders				
Anaemia [A] †	0/783 (0%)	0/795 (0%)	1/691 (0.14%)	2/689 (0.29%)
Iron Deficiency Anaemia [A] †	0/783 (0%)	0/795 (0%)	1/691 (0.14%)	0/689 (0%)
Cardiac disorders				
Acute Coronary Syndrome [A] †	1/783 (0.13%)	0/795 (0%)	2/691 (0.29%)	2/689 (0.29%)
Acute Myocardial Infarction [A] †	0/783 (0%)	1/795 (0.13%)	5/691 (0.72%)	6/689 (0.87%)
Angina Pectoris [A] †	5/783 (0.64%)	5/795 (0.63%)	25/691 (3.62%)	28/689 (4.06%)
Angina Unstable [A] †	0/783 (0%)	2/795 (0.25%)	17/691 (2.46%)	11/689 (1.6%)
Arteriosclerosis Coronary Artery [A] †	0/783 (0%)	0/795 (0%)	1/691 (0.14%)	1/689 (0.15%)
Atrial Fibrillation [A] †	0/783 (0%)	1/795 (0.13%)	3/691 (0.43%)	6/689 (0.87%)
Atrial Flutter [A] †	0/783 (0%)	0/795 (0%)	0/691 (0%)	1/689 (0.15%)
Bradycardia [A] †	0/783 (0%)	2/795 (0.25%)	1/691 (0.14%)	2/689 (0.29%)
Cardiac Failure [A] †	0/783 (0%)	0/795 (0%)	1/691 (0.14%)	0/689 (0%)
Cardiac Failure Congestive [A] †	1/783 (0.13%)	0/795 (0%)	0/691 (0%)	1/689 (0.15%)
Cardiomyopathy [A] †	0/783 (0%)	0/795 (0%)	0/691 (0%)	1/689 (0.15%)
Coronary Artery Disease [A] †	0/783 (0%)	0/795 (0%)	10/691 (1.45%)	4/689 (0.58%)
Coronary Artery Insufficiency [A] †	0/783 (0%)	0/795 (0%)	1/691 (0.14%)	0/689 (0%)

	Rosuvastatin 20 mg	Atorvastatin 40 mg	Rosuvastatin 40 mg	Atorvastatin 80 mg
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Coronary Artery Occlusion [A] †	0/783 (0%)	0/795 (0%)	1/691 (0.14%)	0/689 (0%)
Coronary Artery Stenosis [A] †	1/783 (0.13%)	0/795 (0%)	12/691 (1.74%)	9/689 (1.31%)
Coronary Artery Thrombosis [A] †	0/783 (0%)	0/795 (0%)	1/691 (0.14%)	0/689 (0%)
Ischaemic Cardiomyopathy [A] †	0/783 (0%)	0/795 (0%)	1/691 (0.14%)	0/689 (0%)
Mitral Valve Incompetence [A] †	0/783 (0%)	0/795 (0%)	3/691 (0.43%)	0/689 (0%)
Myocardial Infarction [A] †	1/783 (0.13%)	0/795 (0%)	5/691 (0.72%)	3/689 (0.44%)
Myocardial Ischaemia [A] †	0/783 (0%)	0/795 (0%)	2/691 (0.29%)	0/689 (0%)
Palpitations [A] †	0/783 (0%)	0/795 (0%)	0/691 (0%)	3/689 (0.44%)
Pericardial Rub [A] †	0/783 (0%)	0/795 (0%)	0/691 (0%)	1/689 (0.15%)
Pericarditis [A] †	1/783 (0.13%)	0/795 (0%)	1/691 (0.14%)	1/689 (0.15%)
Sick Sinus Syndrome [A] †	0/783 (0%)	0/795 (0%)	1/691 (0.14%)	2/689 (0.29%)
Sinus Arrest [A] †	0/783 (0%)	0/795 (0%)	1/691 (0.14%)	0/689 (0%)
Wolff-Parkinson-White Syndrome [A] †	0/783 (0%)	0/795 (0%)	0/691 (0%)	1/689 (0.15%)
Congenital, familial and genetic disorders				
Congenital Coronary Artery Malformation [A] †	0/783 (0%)	0/795 (0%)	1/691 (0.14%)	0/689 (0%)
Hip Dysplasia [A] †	0/783 (0%)	0/795 (0%)	0/691 (0%)	1/689 (0.15%)
Ear and labyrinth disorders				
Vertigo [A] †	0/783 (0%)	0/795 (0%)	0/691 (0%)	2/689 (0.29%)
Vertigo Positional [A] †	0/783 (0%)	0/795 (0%)	0/691 (0%)	1/689 (0.15%)
Endocrine disorders				
Basedow's Disease [A] †	0/783 (0%)	0/795 (0%)	1/691 (0.14%)	0/689 (0%)
Eye disorders				

	Rosuvastatin 20 mg	Atorvastatin 40 mg	Rosuvastatin 40 mg	Atorvastatin 80 mg
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Cataract [A] †	0/783 (0%)	0/795 (0%)	1/691 (0.14%)	0/689 (0%)
Retinal Detachment [A] †	0/783 (0%)	0/795 (0%)	1/691 (0.14%)	0/689 (0%)
Gastrointestinal disorders				
Abdominal Pain [A] †	1/783 (0.13%)	0/795 (0%)	2/691 (0.29%)	1/689 (0.15%)
Abdominal Pain Lower [A] †	0/783 (0%)	0/795 (0%)	2/691 (0.29%)	0/689 (0%)
Abdominal Pain Upper [A] †	0/783 (0%)	0/795 (0%)	0/691 (0%)	2/689 (0.29%)
Colitis [A] †	0/783 (0%)	0/795 (0%)	0/691 (0%)	1/689 (0.15%)
Colitis Ulcerative [A] †	0/783 (0%)	0/795 (0%)	0/691 (0%)	1/689 (0.15%)
Colonic Polyp [A] †	0/783 (0%)	0/795 (0%)	1/691 (0.14%)	1/689 (0.15%)
Constipation [A] †	0/783 (0%)	0/795 (0%)	0/691 (0%)	1/689 (0.15%)
Diarrhoea [A] †	0/783 (0%)	0/795 (0%)	0/691 (0%)	1/689 (0.15%)
Enteritis [A] †	0/783 (0%)	0/795 (0%)	1/691 (0.14%)	0/689 (0%)
Erosive Oesophagitis [A] †	0/783 (0%)	0/795 (0%)	1/691 (0.14%)	0/689 (0%)
Gastric Polyps [A] †	0/783 (0%)	0/795 (0%)	1/691 (0.14%)	0/689 (0%)
Gastric Ulcer [A] †	0/783 (0%)	0/795 (0%)	1/691 (0.14%)	0/689 (0%)
Gastritis [A] †	0/783 (0%)	0/795 (0%)	0/691 (0%)	1/689 (0.15%)
Gastrointestinal Haemorrhage [A] †	0/783 (0%)	0/795 (0%)	4/691 (0.58%)	0/689 (0%)
Haematemesis [A] †	0/783 (0%)	0/795 (0%)	0/691 (0%)	1/689 (0.15%)
Ileus [A] †	0/783 (0%)	0/795 (0%)	1/691 (0.14%)	0/689 (0%)
Inguinal Hernia [A] †	0/783 (0%)	0/795 (0%)	1/691 (0.14%)	2/689 (0.29%)
Nausea [A] †	0/783 (0%)	0/795 (0%)	0/691 (0%)	1/689 (0.15%)
Oesophagitis [A] †	0/783 (0%)	0/795 (0%)	1/691 (0.14%)	0/689 (0%)

	Rosuvastatin 20 mg	Atorvastatin 40 mg	Rosuvastatin 40 mg	Atorvastatin 80 mg
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Pancreatitis [A] †	0/783 (0%)	0/795 (0%)	0/691 (0%)	2/689 (0.29%)
Retroperitoneal Haematoma [A] †	0/783 (0%)	1/795 (0.13%)	1/691 (0.14%)	0/689 (0%)
Retroperitoneal Haemorrhage [A] †	0/783 (0%)	0/795 (0%)	1/691 (0.14%)	0/689 (0%)
Umbilical Hernia, Obstructive [A] †	0/783 (0%)	0/795 (0%)	1/691 (0.14%)	0/689 (0%)
Upper Gastrointestinal Haemorrhage [A] †	0/783 (0%)	0/795 (0%)	0/691 (0%)	1/689 (0.15%)
General disorders				
Chest Discomfort [A] †	0/783 (0%)	0/795 (0%)	1/691 (0.14%)	0/689 (0%)
Chest Pain [A] †	0/783 (0%)	0/795 (0%)	7/691 (1.01%)	7/689 (1.02%)
Device Malfunction [A] †	0/783 (0%)	0/795 (0%)	1/691 (0.14%)	0/689 (0%)
Device Occlusion [A] †	0/783 (0%)	0/795 (0%)	1/691 (0.14%)	0/689 (0%)
Device Stimulation Issue [A] †	0/783 (0%)	0/795 (0%)	1/691 (0.14%)	0/689 (0%)
Hernia Pain [A] †	0/783 (0%)	0/795 (0%)	1/691 (0.14%)	0/689 (0%)
Non-Cardiac Chest Pain [A] †	1/783 (0.13%)	3/795 (0.38%)	14/691 (2.03%)	7/689 (1.02%)
Pyrexia [A] †	0/783 (0%)	0/795 (0%)	1/691 (0.14%)	0/689 (0%)
Sudden Death [A] †	0/783 (0%)	0/795 (0%)	0/691 (0%)	1/689 (0.15%)
Thrombosis In Device [A] †	1/783 (0.13%)	0/795 (0%)	0/691 (0%)	0/689 (0%)
Hepatobiliary disorders				
Cholecystitis [A] †	0/783 (0%)	0/795 (0%)	0/691 (0%)	1/689 (0.15%)
Cholecystitis Acute [A] †	0/783 (0%)	0/795 (0%)	1/691 (0.14%)	1/689 (0.15%)
Cholelithiasis [A] †	0/783 (0%)	0/795 (0%)	4/691 (0.58%)	1/689 (0.15%)
Jaundice [A] †	0/783 (0%)	0/795 (0%)	1/691 (0.14%)	0/689 (0%)
Infections and infestations				

	Rosuvastatin 20 mg	Atorvastatin 40 mg	Rosuvastatin 40 mg	Atorvastatin 80 mg
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Appendicitis [A] †	0/783 (0%)	0/795 (0%)	1/691 (0.14%)	1/689 (0.15%)
Appendicitis Perforated [A] †	0/783 (0%)	0/795 (0%)	1/691 (0.14%)	0/689 (0%)
Arthritis Bacterial [A] †	0/783 (0%)	0/795 (0%)	1/691 (0.14%)	0/689 (0%)
Bronchitis [A] †	0/783 (0%)	0/795 (0%)	1/691 (0.14%)	0/689 (0%)
Cellulitis [A] †	0/783 (0%)	0/795 (0%)	1/691 (0.14%)	1/689 (0.15%)
Dengue Fever [A] †	0/783 (0%)	0/795 (0%)	1/691 (0.14%)	0/689 (0%)
Gastroenteritis [A] †	1/783 (0.13%)	0/795 (0%)	0/691 (0%)	2/689 (0.29%)
Groin Infection [A] †	0/783 (0%)	1/795 (0.13%)	0/691 (0%)	0/689 (0%)
Herpes Zoster Infection Neurological [A] †	0/783 (0%)	0/795 (0%)	1/691 (0.14%)	0/689 (0%)
Lower Respiratory Tract Infection [A] †	0/783 (0%)	0/795 (0%)	1/691 (0.14%)	1/689 (0.15%)
Pilonidal Cyst [A] †	0/783 (0%)	0/795 (0%)	1/691 (0.14%)	0/689 (0%)
Pneumonia [A] †	0/783 (0%)	1/795 (0.13%)	4/691 (0.58%)	2/689 (0.29%)
Puncture Site Infection [A] †	0/783 (0%)	1/795 (0.13%)	0/691 (0%)	0/689 (0%)
Staphylococcal Abscess [A] †	0/783 (0%)	0/795 (0%)	1/691 (0.14%)	0/689 (0%)
Upper Respiratory Tract Infection [A] †	0/783 (0%)	0/795 (0%)	0/691 (0%)	1/689 (0.15%)
Urinary Tract Infection [A] †	0/783 (0%)	0/795 (0%)	3/691 (0.43%)	2/689 (0.29%)
Urosepsis [A] †	0/783 (0%)	0/795 (0%)	2/691 (0.29%)	0/689 (0%)
Injury, poisoning and procedural complications				
Ankle Fracture [A] †	0/783 (0%)	0/795 (0%)	2/691 (0.29%)	1/689 (0.15%)
Coronary Artery Restenosis [A] †	0/783 (0%)	0/795 (0%)	1/691 (0.14%)	1/689 (0.15%)
Fall [A] †	0/783 (0%)	0/795 (0%)	0/691 (0%)	1/689 (0.15%)
Femur Fracture [A] †	0/783 (0%)	0/795 (0%)	0/691 (0%)	1/689 (0.15%)

	Rosuvastatin 20 mg	Atorvastatin 40 mg	Rosuvastatin 40 mg	Atorvastatin 80 mg
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Fractured Coccyx [A] †	0/783 (0%)	0/795 (0%)	1/691 (0.14%)	0/689 (0%)
Hand Fracture [A] †	0/783 (0%)	0/795 (0%)	1/691 (0.14%)	0/689 (0%)
Head Injury [A] †	0/783 (0%)	0/795 (0%)	1/691 (0.14%)	1/689 (0.15%)
Heat Exhaustion [A] †	0/783 (0%)	0/795 (0%)	0/691 (0%)	1/689 (0.15%)
In-Stent Arterial Restenosis [A] †	0/783 (0%)	0/795 (0%)	0/691 (0%)	1/689 (0.15%)
In-Stent Coronary Artery Restenosis [A] †	0/783 (0%)	0/795 (0%)	6/691 (0.87%)	3/689 (0.44%)
Injury [A] †	0/783 (0%)	0/795 (0%)	0/691 (0%)	1/689 (0.15%)
Intentional Overdose [A] †	0/783 (0%)	0/795 (0%)	0/691 (0%)	1/689 (0.15%)
Joint Dislocation [A] †	0/783 (0%)	0/795 (0%)	1/691 (0.14%)	0/689 (0%)
Laceration [A] †	0/783 (0%)	0/795 (0%)	0/691 (0%)	1/689 (0.15%)
Limb Injury [A] †	0/783 (0%)	0/795 (0%)	1/691 (0.14%)	0/689 (0%)
Lower Limb Fracture [A] †	0/783 (0%)	0/795 (0%)	1/691 (0.14%)	0/689 (0%)
Overdose [A] †	0/783 (0%)	1/795 (0.13%)	0/691 (0%)	0/689 (0%)
Pelvic Fracture [A] †	0/783 (0%)	0/795 (0%)	1/691 (0.14%)	0/689 (0%)
Post Procedural Haemorrhage [A] †	0/783 (0%)	0/795 (0%)	1/691 (0.14%)	0/689 (0%)
Post Procedural Myocardial Infarction [A] †	0/783 (0%)	1/795 (0.13%)	0/691 (0%)	0/689 (0%)
Pseudomeningocele [A] †	0/783 (0%)	0/795 (0%)	0/691 (0%)	1/689 (0.15%)
Road Traffic Accident [A] †	0/783 (0%)	0/795 (0%)	1/691 (0.14%)	0/689 (0%)
Thermal Burn [A] †	0/783 (0%)	0/795 (0%)	0/691 (0%)	1/689 (0.15%)
Toxicity To Various Agents [A] †	0/783 (0%)	0/795 (0%)	2/691 (0.29%)	0/689 (0%)
Traumatic Lung Injury [A] †	0/783 (0%)	0/795 (0%)	1/691 (0.14%)	0/689 (0%)
Investigations				

	Rosuvastatin 20 mg	Atorvastatin 40 mg	Rosuvastatin 40 mg	Atorvastatin 80 mg
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Blood Pressure Increased [A] †	0/783 (0%)	0/795 (0%)	0/691 (0%)	2/689 (0.29%)
Cardiac Stress Test Abnormal [A] †	1/783 (0.13%)	0/795 (0%)	0/691 (0%)	0/689 (0%)
Heart Rate Irregular [A] †	0/783 (0%)	0/795 (0%)	1/691 (0.14%)	0/689 (0%)
Liver Function Test Abnormal [A] †	0/783 (0%)	0/795 (0%)	0/691 (0%)	1/689 (0.15%)
Occult Blood Positive [A] †	0/783 (0%)	0/795 (0%)	1/691 (0.14%)	0/689 (0%)
Transaminases Increased [A] †	0/783 (0%)	0/795 (0%)	0/691 (0%)	1/689 (0.15%)
Metabolism and nutrition disorders				
Diabetes Mellitus [A] †	0/783 (0%)	0/795 (0%)	2/691 (0.29%)	0/689 (0%)
Hyperglycaemia [A] †	0/783 (0%)	0/795 (0%)	0/691 (0%)	1/689 (0.15%)
Hypoglycaemia [A] †	0/783 (0%)	0/795 (0%)	1/691 (0.14%)	2/689 (0.29%)
Obesity [A] †	0/783 (0%)	0/795 (0%)	1/691 (0.14%)	1/689 (0.15%)
Type 2 Diabetes Mellitus [A] †	0/783 (0%)	0/795 (0%)	0/691 (0%)	1/689 (0.15%)
Musculoskeletal and connective tissue disorders				
Arthralgia [A] †	0/783 (0%)	0/795 (0%)	1/691 (0.14%)	1/689 (0.15%)
Back Pain [A] †	0/783 (0%)	0/795 (0%)	1/691 (0.14%)	1/689 (0.15%)
Bone Loss [A] †	0/783 (0%)	0/795 (0%)	0/691 (0%)	1/689 (0.15%)
Bone Pain [A] †	0/783 (0%)	0/795 (0%)	0/691 (0%)	2/689 (0.29%)
Floating Patella [A] †	0/783 (0%)	0/795 (0%)	1/691 (0.14%)	0/689 (0%)
Foot Deformity [A] †	0/783 (0%)	0/795 (0%)	0/691 (0%)	1/689 (0.15%)
Groin Pain [A] †	0/783 (0%)	0/795 (0%)	1/691 (0.14%)	0/689 (0%)
Intervertebral Disc Disorder [A] †	0/783 (0%)	0/795 (0%)	0/691 (0%)	1/689 (0.15%)
Intervertebral Disc Protrusion [A] †	0/783 (0%)	0/795 (0%)	2/691 (0.29%)	0/689 (0%)

	Rosuvastatin 20 mg	Atorvastatin 40 mg	Rosuvastatin 40 mg	Atorvastatin 80 mg
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Muscle Spasms [A] †	0/783 (0%)	1/795 (0.13%)	0/691 (0%)	0/689 (0%)
Musculoskeletal Chest Pain [A] †	1/783 (0.13%)	0/795 (0%)	4/691 (0.58%)	0/689 (0%)
Musculoskeletal Pain [A] †	0/783 (0%)	0/795 (0%)	1/691 (0.14%)	0/689 (0%)
Myalgia [A] †	0/783 (0%)	0/795 (0%)	1/691 (0.14%)	3/689 (0.44%)
Myopathy [A] †	0/783 (0%)	0/795 (0%)	0/691 (0%)	1/689 (0.15%)
Osteoarthritis [A] †	0/783 (0%)	0/795 (0%)	6/691 (0.87%)	2/689 (0.29%)
Osteonecrosis [A] †	0/783 (0%)	0/795 (0%)	1/691 (0.14%)	0/689 (0%)
Rotator Cuff Syndrome [A] †	0/783 (0%)	0/795 (0%)	2/691 (0.29%)	0/689 (0%)
Spinal Column Stenosis [A] †	0/783 (0%)	0/795 (0%)	0/691 (0%)	1/689 (0.15%)
Spondylitis [A] †	0/783 (0%)	0/795 (0%)	1/691 (0.14%)	0/689 (0%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
Adenocarcinoma [A] †	0/783 (0%)	0/795 (0%)	0/691 (0%)	1/689 (0.15%)
Bladder Neoplasm [A] †	0/783 (0%)	0/795 (0%)	1/691 (0.14%)	0/689 (0%)
Breast Cancer [A] †	0/783 (0%)	0/795 (0%)	1/691 (0.14%)	0/689 (0%)
Colon Adenoma [A] †	0/783 (0%)	0/795 (0%)	0/691 (0%)	1/689 (0.15%)
Extranodal Marginal Zone B-Cell Lymphoma (Malt Type) [A] †	0/783 (0%)	0/795 (0%)	1/691 (0.14%)	0/689 (0%)
Eyelid Tumour [A] †	0/783 (0%)	0/795 (0%)	1/691 (0.14%)	0/689 (0%)
Gallbladder Cancer [A] †	0/783 (0%)	0/795 (0%)	1/691 (0.14%)	0/689 (0%)
Lung Adenocarcinoma [A] †	0/783 (0%)	0/795 (0%)	1/691 (0.14%)	0/689 (0%)
Lung Cancer Metastatic [A] †	0/783 (0%)	0/795 (0%)	1/691 (0.14%)	0/689 (0%)
Neoplasm [A] †	0/783 (0%)	0/795 (0%)	1/691 (0.14%)	0/689 (0%)

	Rosuvastatin 20 mg	Atorvastatin 40 mg	Rosuvastatin 40 mg	Atorvastatin 80 mg
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Neoplasm Prostate [A] †	1/783 (0.13%)	0/795 (0%)	0/691 (0%)	0/689 (0%)
Prostate Cancer [A] †	0/783 (0%)	0/795 (0%)	2/691 (0.29%)	2/689 (0.29%)
Throat Cancer [A] †	0/783 (0%)	0/795 (0%)	1/691 (0.14%)	0/689 (0%)
Uterine Leiomyoma [A] †	0/783 (0%)	0/795 (0%)	1/691 (0.14%)	1/689 (0.15%)
Nervous system disorders				
Carotid Artery Stenosis [A] †	0/783 (0%)	0/795 (0%)	2/691 (0.29%)	0/689 (0%)
Cerebral Haemorrhage [A] †	0/783 (0%)	0/795 (0%)	0/691 (0%)	1/689 (0.15%)
Cerebrovascular Accident [A] †	0/783 (0%)	0/795 (0%)	2/691 (0.29%)	2/689 (0.29%)
Complicated Migraine [A] †	0/783 (0%)	0/795 (0%)	0/691 (0%)	1/689 (0.15%)
Convulsion [A] †	0/783 (0%)	0/795 (0%)	1/691 (0.14%)	0/689 (0%)
Dizziness [A] †	1/783 (0.13%)	0/795 (0%)	1/691 (0.14%)	2/689 (0.29%)
Grand Mal Convulsion [A] †	0/783 (0%)	0/795 (0%)	1/691 (0.14%)	0/689 (0%)
Haemorrhage Intracranial [A] †	0/783 (0%)	0/795 (0%)	0/691 (0%)	1/689 (0.15%)
Haemorrhagic Stroke [A] †	0/783 (0%)	0/795 (0%)	1/691 (0.14%)	0/689 (0%)
Intracranial Hypotension [A] †	0/783 (0%)	0/795 (0%)	0/691 (0%)	1/689 (0.15%)
Ischaemic Stroke [A] †	0/783 (0%)	0/795 (0%)	2/691 (0.29%)	0/689 (0%)
Neuropathy Peripheral [A] †	0/783 (0%)	0/795 (0%)	1/691 (0.14%)	0/689 (0%)
Presyncope [A] †	0/783 (0%)	0/795 (0%)	0/691 (0%)	3/689 (0.44%)
Radiculopathy [A] †	0/783 (0%)	0/795 (0%)	1/691 (0.14%)	0/689 (0%)
Syncope [A] †	0/783 (0%)	0/795 (0%)	3/691 (0.43%)	6/689 (0.87%)
Transient Ischaemic Attack [A] †	0/783 (0%)	1/795 (0.13%)	2/691 (0.29%)	1/689 (0.15%)
Tremor [A] †	0/783 (0%)	0/795 (0%)	1/691 (0.14%)	0/689 (0%)

	Rosuvastatin 20 mg	Atorvastatin 40 mg	Rosuvastatin 40 mg	Atorvastatin 80 mg
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Psychiatric disorders				
Anxiety [A] †	0/783 (0%)	0/795 (0%)	1/691 (0.14%)	0/689 (0%)
Confusional State [A] †	0/783 (0%)	0/795 (0%)	0/691 (0%)	1/689 (0.15%)
Dependence [A] †	0/783 (0%)	0/795 (0%)	0/691 (0%)	1/689 (0.15%)
Depression [A] †	0/783 (0%)	0/795 (0%)	3/691 (0.43%)	0/689 (0%)
Panic Attack [A] †	0/783 (0%)	0/795 (0%)	1/691 (0.14%)	0/689 (0%)
Suicidal Ideation [A] †	0/783 (0%)	0/795 (0%)	1/691 (0.14%)	0/689 (0%)
Renal and urinary disorders				
Bladder Neck Obstruction [A] †	1/783 (0.13%)	0/795 (0%)	0/691 (0%)	0/689 (0%)
Calculus Bladder [A] †	0/783 (0%)	0/795 (0%)	1/691 (0.14%)	0/689 (0%)
Haematuria [A] †	0/783 (0%)	0/795 (0%)	2/691 (0.29%)	2/689 (0.29%)
Nephrolithiasis [A] †	0/783 (0%)	0/795 (0%)	3/691 (0.43%)	0/689 (0%)
Renal Failure Acute [A] †	0/783 (0%)	0/795 (0%)	1/691 (0.14%)	0/689 (0%)
Ureteric Stenosis [A] †	0/783 (0%)	0/795 (0%)	1/691 (0.14%)	0/689 (0%)
Urinary Retention [A] †	0/783 (0%)	0/795 (0%)	1/691 (0.14%)	0/689 (0%)
Reproductive system and breast disorders				
Benign Prostatic Hyperplasia [A] †	0/783 (0%)	0/795 (0%)	0/691 (0%)	1/689 (0.15%)
Cystocele [A] †	0/783 (0%)	0/795 (0%)	0/691 (0%)	1/689 (0.15%)
Gynaecomastia [A] †	0/783 (0%)	0/795 (0%)	1/691 (0.14%)	0/689 (0%)
Vaginal Haemorrhage [A] †	1/783 (0.13%)	0/795 (0%)	0/691 (0%)	1/689 (0.15%)
Respiratory, thoracic and mediastinal disorders				
Acute Respiratory Failure [A] †	0/783 (0%)	0/795 (0%)	1/691 (0.14%)	0/689 (0%)
Asthma [A] †	0/783 (0%)	0/795 (0%)	0/691 (0%)	1/689 (0.15%)

	Rosuvastatin 20 mg	Atorvastatin 40 mg	Rosuvastatin 40 mg	Atorvastatin 80 mg
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Chronic Obstructive Pulmonary Disease [A] †	0/783 (0%)	0/795 (0%)	3/691 (0.43%)	2/689 (0.29%)
Dyspnoea [A] †	0/783 (0%)	0/795 (0%)	3/691 (0.43%)	3/689 (0.44%)
Epistaxis [A] †	0/783 (0%)	1/795 (0.13%)	0/691 (0%)	0/689 (0%)
Haemoptysis [A] †	0/783 (0%)	0/795 (0%)	1/691 (0.14%)	0/689 (0%)
Haemothorax [A] †	0/783 (0%)	0/795 (0%)	1/691 (0.14%)	0/689 (0%)
Hypoxia [A] †	0/783 (0%)	0/795 (0%)	1/691 (0.14%)	0/689 (0%)
Nasal Obstruction [A] †	0/783 (0%)	0/795 (0%)	0/691 (0%)	1/689 (0.15%)
Nasal Polyps [A] †	0/783 (0%)	0/795 (0%)	0/691 (0%)	1/689 (0.15%)
Pneumonia Aspiration [A] †	0/783 (0%)	0/795 (0%)	1/691 (0.14%)	0/689 (0%)
Pulmonary Embolism [A] †	0/783 (0%)	0/795 (0%)	1/691 (0.14%)	2/689 (0.29%)
Pulmonary Mass [A] †	0/783 (0%)	0/795 (0%)	0/691 (0%)	1/689 (0.15%)
Pulmonary Oedema [A] †	1/783 (0.13%)	0/795 (0%)	0/691 (0%)	0/689 (0%)
Respiratory Failure [A] †	0/783 (0%)	0/795 (0%)	0/691 (0%)	1/689 (0.15%)
Sleep Apnoea Syndrome [A] †	0/783 (0%)	1/795 (0.13%)	0/691 (0%)	1/689 (0.15%)
Skin and subcutaneous tissue disorders				
Skin Ulcer [A] †	0/783 (0%)	0/795 (0%)	0/691 (0%)	1/689 (0.15%)
Surgical and medical procedures				
Coronary Arterial Stent Insertion [A] †	0/783 (0%)	0/795 (0%)	1/691 (0.14%)	0/689 (0%)
Vascular disorders				
Aortic Stenosis [A] †	0/783 (0%)	0/795 (0%)	1/691 (0.14%)	0/689 (0%)
Arterial Occlusive Disease [A] †	0/783 (0%)	0/795 (0%)	0/691 (0%)	1/689 (0.15%)
Arterial Stenosis [A] †	0/783 (0%)	0/795 (0%)	0/691 (0%)	1/689 (0.15%)

	Rosuvastatin 20 mg	Atorvastatin 40 mg	Rosuvastatin 40 mg	Atorvastatin 80 mg
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Arteriosclerosis [A] †	0/783 (0%)	0/795 (0%)	1/691 (0.14%)	0/689 (0%)
Deep Vein Thrombosis [A] †	0/783 (0%)	1/795 (0.13%)	1/691 (0.14%)	0/689 (0%)
Femoral Arterial Stenosis [A] †	0/783 (0%)	0/795 (0%)	0/691 (0%)	1/689 (0.15%)
Haematoma [A] †	0/783 (0%)	0/795 (0%)	1/691 (0.14%)	0/689 (0%)
Hypertension [A] †	1/783 (0.13%)	0/795 (0%)	1/691 (0.14%)	1/689 (0.15%)
Iliac Artery Stenosis [A] †	1/783 (0.13%)	0/795 (0%)	0/691 (0%)	0/689 (0%)
Intermittent Claudication [A] †	0/783 (0%)	0/795 (0%)	2/691 (0.29%)	1/689 (0.15%)
Peripheral Ischaemia [A] †	0/783 (0%)	0/795 (0%)	0/691 (0%)	1/689 (0.15%)
Subclavian Artery Stenosis [A] †	0/783 (0%)	0/795 (0%)	2/691 (0.29%)	0/689 (0%)
Thrombophlebitis Superficial [A] †	0/783 (0%)	0/795 (0%)	0/691 (0%)	1/689 (0.15%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA 14.0

Other Adverse Events

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

	Rosuvastatin 20 mg	Atorvastatin 40 mg	Rosuvastatin 40 mg	Atorvastatin 80 mg
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	0/783 (0%)	0/795 (0%)	210/691 (30.39%)	213/689 (30.91%)
Cardiac disorders				
ANGINA PECTORIS [A] †	0/783 (0%)	0/795 (0%)	61/691 (8.83%)	65/689 (9.43%)
General disorders				
FATIGUE [A] †	0/783 (0%)	0/795 (0%)	32/691 (4.63%)	39/689 (5.66%)
Musculoskeletal and connective tissue disorders				
ARTHRALGIA [A] †	0/783 (0%)	0/795 (0%)	50/691 (7.24%)	43/689 (6.24%)
MYALGIA [A] †	0/783 (0%)	0/795 (0%)	99/691 (14.33%)	91/689 (13.21%)

	Rosuvastatin 20 mg	Atorvastatin 40 mg	Rosuvastatin 40 mg	Atorvastatin 80 mg
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Vascular disorders				
HYPERTENSION [A] †	0/783 (0%)	0/795 (0%)	36/691 (5.21%)	40/689 (5.81%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA 14.0

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.

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