ClinicalTrials.gov Protocol and Results Registration System (PRS) Receipt
Release Date: 11/25/2013

ClinicalTrials.gov ID: NCT00631189

Study Identification

Unique Protocol ID:	D3560L00068
Brief Title:	Evaluation of the Efficacy and Safety of Rosuvastatin 5 mg Versus Pravastatin 40 mg and Atorvastatin 10 mg in Type IIa and IIb Hypercholesterolaemic Patients (CAP-Chol)
Official Title:	Evaluation of the Efficacy and Safety of Rosuvastatin 5 mg Versus Pravastatin 40 mg and Atorvastatin 10 mg in Subjects With Type IIa and IIb Hypercholesterolaemia
Secondary IDs:	EudraCT No 2006-006697-15

Study Status

Record Verification:	June 2011
Overall Status:	Completed
Study Start:	October 2007
Primary Completion:	October 2008 [Actual]
Study Completion:	October 2008 [Actual]

Sponsor/Collaborators

Sponsor:	AstraZeneca
Responsible Party:	
Collaborators:	

Oversight

FDA Regulated?:	Yes

Applicable Trial?:	Section 801 Clinical Trial? Yes Delayed Posting? No
IND/IDE Protocol?:	No
Review Board:	Approval Status: Approved Approval Number: 2007/05 Board Name: Comité de Protection des Personnes Est I Board Affiliation: French Health Products Safety Agency Phone: 33 3 80 66 62 09 Email:
Data Monitoring?:	No
Plan to Share Data?:	
Oversight Authorities:	France: Afssaps - Agence française de sécurité sanitaire des produits de santé (Saint-Denis)

Study Description

Brief Summary:	The purpose of this study is to evaluate the efficacy and safety of Rosuvastatin 5 mg as an hypercholesterolemia treatment comparatively at 2 other statins: Pravastatin 40 mg and Atorvastatin 10 mg. Treatment efficacy will be evaluated by the percentage of LDL-C variation after 8 weeks of treatment.
Detailed Description:	

Conditions

Conditions:	Type IIa and IIb Hypercholesterolaemia
Keywords:	dyslipidemia

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 4
Intervention Model:	Parallel Assignment
Number of Arms:	2
Masking:	Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor)
Allocation:	Randomized

Endpoint Classification: Safety/Efficacy Study

Enrollment: 668 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Active Comparator: 1 Rosuvastatin and Pravastatin	Drug: Rosuvastatin 5mg oral Other Names: • Crestor Drug: Pravastatin 40mg oral Other Names: • Prevachol
Active Comparator: 2 Rosuvastatin and Atorvastatin	Drug: Rosuvastatin 5mg oral Other Names: • Crestor Drug: Atorvastatin 10mg oral Other Names: • Lipitor

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age: 18 Years

Maximum Age:

Gender: Both

Accepts Healthy Volunteers?: No

Criteria: Inclusion Criteria:

- subjects presenting type IIa or IIb primary hypercholesterolaemia diagnosed for at least 3 months, in a context of primary prevention with at least two associated cardiovascular risk factors and: (i)either "naive" to all lipid-lowering therapy, (ii)or treated with a statin (treatment ongoing or stopped during the previous 8 weeks)

Exclusion Criteria:

- homozygous or heterozygous familial hypercholesterolaemia
- hypertriglyceridaemia (TG ≥ 4 g/l)
- subjects at high cardiovascular risk according to the AFSSAPS 2005 definition (coronary artery disease or history of documented vascular disease, high cardiovascular risk type 2 diabetes, subject in primary prevention with a 10-year CHD risk > 20%)
- history of adverse events or hypersensitivity to an HMG Co-A reductase inhibitor (particularly a history of myopathy)
- concomitant use of any drugs not authorized during the study
- active liver disease with elevation of serum transaminases (ASAT, ALAT) more than twice the upper limit of normal
- CPK more than 3 times the upper limit of normal
- moderate or severe renal failure (creatinine clearance < 6 ml/min)
- poorly controlled hypothyroidism; poorly controlled hypertension (DBP > 95 mm Hg and/or SBP > 180 mm Hg)

Contacts/Locations

Study Officials: Michel Farnier, MD
Study Principal Investigator
Le Point Medical - Rond Point du Jour

Locations: France
Research Site
Aix En Provence, France

Research Site
Allaire, France

Research Site
Amiens, France

Research Site
Ancerville, France

Research Site
Angers, France

Research Site
Annecy, France

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Anzin, France

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Arles, France

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Arthez de Bearn, France

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Aspach Le Bas, France

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Aubagne, France

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Bruges, France

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Cabanac Et Villagrains, France

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Saint Medard En Jalles, France

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Semur En Auxois, France

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St Etienne de Montluc, France

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St Girons, France

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St Jean de Braye, France

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St Leu La Foret, France

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St Morillon, France

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St Remy de Provence, France

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St. Emilion, France

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Strasbourg, France

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Trie Sur Baise, France

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Varces Allieres Et Risset, France

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Vatan, France

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Wattignies, France

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Wattrelos, France

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Yerres, France

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Yffiniac, France

References

Citations:

Links:

Study Data/Documents:

Study Results

Participant Flow

Recruitment Details	Patients were recruited by general practitioner. First patient included: 12 October 2007 Last patient terminated the study: 04 October 2008

Pre-Assignment Details	This French multicentre, randomized double-blind study was conducted on three parallel arms. The 14-week study comprised 3 visits: a screening visit (week 0, V1), a randomization and treatment allocation visit (week 6, V2) and an evaluation visit (week 14, V3). Patients were randomized at V2 and were treated for a period of 8 weeks.

Reporting Groups

	Description
Initial Phase	Initial phase (between V1 and V2)
Atorvastatin	Atorvastatin 10 mg
Pravastatin	Pravastatin 40 mg
Rosuvastatin	Rosuvastatin 5 mg

Initial Phase

	Initial Phase	Atorvastatin	Pravastatin	Rosuvastatin
Started	668	0 [1]	0 [1]	0 [1]
Completed	317	0 [1]	0 [1]	0 [1]
Not Completed	351	0	0	0
Protocol Violation	347	0	0	0
Withdrawal by Subject	4	0	0	0

[1] Not applicable

Treatment Phase

	Initial Phase	Atorvastatin	Pravastatin	Rosuvastatin
Started	0 [1]	104	103	110
Completed	0 [1]	97	92	103
Not Completed	0	7	11	7
Withdrawal by Subject	0	2	1	1
Protocol Violation	0	1	6	2
Adverse Event	0	3	2	4
Lost to Follow-up	0	1	0	0

	Initial Phase	Atorvastatin	Pravastatin	Rosuvastatin
Pregnancy	0	0	1	0
patient did not take pravastatin	0	0	1	0

[1] not applicable

Baseline Characteristics

Reporting Groups

	Description
Initial Phase	Initial phase (between V1 and V2)
Atorvastatin	Atorvastatin 10 mg
Pravastatin	Pravastatin 40 mg
Rosuvastatin	Rosuvastatin 5 mg

Baseline Measures

	Initial Phase	Atorvastatin	Pravastatin	Rosuvastatin	Total
Number of Participants	0	104	103	110	317
Age, Continuous [units: years] Mean (Standard Deviation)		57.31 (10.59)	57.23 (10.8)	57.04 (9.32)	57.18 (9.95)
Gender, Male/Female [units: Participants]					
Female		49	55	46	150
Male		55	48	64	167

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Change in Low Density Lipoprotein Cholesterol (LDL-C) Level After 8 Weeks
Measure Description	To compare the percentages of LDL-C level variation. As the recruitment target was not reached at the date initially planned, and in view of the recruitment difficulties, AstraZeneca decided not to extend the patient recruitment period and to perform only a descriptive analysis of the data
Time Frame	Change from baseline and after 8 weeks of treatment

Safety Issue?	No

Analysis Population Description

92 patients completed the study in the Pravastatin group, nevertheless, primary and secondary outcome measures are described on 91 patients in the Pravastatin arm due to one missing data in this group

Reporting Groups

	Description
Initial Phase	Initial phase (between V1 and V2)
Atorvastatin	Atorvastatin 10 mg
Pravastatin	Pravastatin 40 mg
Rosuvastatin	Rosuvastatin 5 mg

Measured Values

	Initial Phase	Atorvastatin	Pravastatin	Rosuvastatin
Number of Participants Analyzed	0	97	91	103
Change in Low Density Lipoprotein Cholesterol (LDL-C) Level After 8 Weeks [units: percentage of LDL-C decrease] Mean (Standard Deviation)		-39.4 (13.77)	-30.3 (15.43)	-37.6 (17.96)

2. Secondary Outcome Measure:

Measure Title	To Compare the Percentage of Patients Reaching the Overall LDL-C Goal According to the French Agency for the Safety of Health Products (AFSSAPS) 2005 Guidelines for the Management of Dyslipidaemic Patients
Measure Description	Not done. As the recruitment target was not reached at the date initially planned, and in view of the recruitment difficulties, AstraZeneca decided not to extend the patient recruitment period and to perform only a descriptive analysis of the data
Time Frame	Not done
Safety Issue?	No

Outcome Measure Data Not Reported

3. Secondary Outcome Measure:

Measure Title	To Compare the Percentage of Patients Reaching the LDL-C Goal, in Relation to the Number of Risk Factors, According to the French Agency for the Safety of Health Products (AFSSAPS) 2005 Guidelines for the Management of Dyslipidaemic Patients
Measure Description	Not done. As the recruitment target was not reached at the date initially planned, and in view of the recruitment difficulties, AstraZeneca decided not to extend the patient recruitment period and to perform only a descriptive analysis of the data
Time Frame	Not done
Safety Issue?	No

Outcome Measure Data Not Reported

4. Secondary Outcome Measure:

Measure Title	Compare the Percentage of Total Cholesterol Variation From Baseline and After 8 Weeks of Treatment
Measure Description	To compare the percentage of total cholesterol variation taking baseline value as a reference. As the recruitment target was not reached at the date initially planned, and in view of the recruitment difficulties, AstraZeneca decided not to extend the patient recruitment period and to perform only a descriptive analysis of the data
Time Frame	from baseline and after 8 weeks of treatment
Safety Issue?	No

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
Initial Phase	Initial phase (between V1 and V2)
Atorvastatin	Atorvastatin 10 mg
Pravastatin	Pravastatin 40 mg
Rosuvastatin	Rosuvastatin 5 mg

Measured Values

	Initial Phase	Atorvastatin	Pravastatin	Rosuvastatin
Number of Participants Analyzed	0	97	91	103
Compare the Percentage of Total Cholesterol Variation From Baseline and After 8 Weeks of Treatment		-28.6 (11.0)	-20.4 (11.7)	-25.2 (14.0)

	Initial Phase	Atorvastatin	Pravastatin	Rosuvastatin
[units: percentage of total cholesterol decrease] Mean (Standard Deviation)				

5. Secondary Outcome Measure:

Measure Title	Compare the Percentage of HDL-C (High Density Lipoprotein Cholesterol) Variation From Baseline and After 8 Weeks of Treatment
Measure Description	Compare the percentage of HDL-C (High Density Lipoprotein Cholesterol) variation taking baseline value as a reference and after 8 weeks of treatment. As the recruitment target was not reached at the date initially planned, and in view of the recruitment difficulties, AstraZeneca decided not to extend the patient recruitment period and to perform only a descriptive analysis of the data
Time Frame	After 8 weeks of treatment
Safety Issue?	No

Analysis Population Description

[Not Specified]

Reporting Groups

	Description
Initial Phase	Initial phase (between V1 and V2)
Atorvastatin	Atorvastatin 10 mg
Pravastatin	Pravastatin 40 mg
Rosuvastatin	Rosuvastatin 5 mg

Measured Values

	Initial Phase	Atorvastatin	Pravastatin	Rosuvastatin
Number of Participants Analyzed	0	97	91	103
Compare the Percentage of HDL-C (High Density Lipoprotein Cholesterol) Variation From Baseline and After 8 Weeks of Treatment [units: percentage of HDL-C increase] Mean (Standard Deviation)		4.4 (14.3)	7.9 (19.2)	11.3 (20.6)

6. Secondary Outcome Measure:

Measure Title	Compare the Percentage of Variation From Baseline Triglycerides Values and After 8 Weeks
Measure Description	To compare the percentage of variation from baseline triglycerides values and after 8 weeks. As the recruitment target was not reached at the date initially planned, and in view of the recruitment difficulties, AstraZeneca decided not to extend the patient recruitment period and to perform only a descriptive analysis of the data
Time Frame	Baseline and after 8 weeks of treatment
Safety Issue?	No

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
Initial Phase	Initial phase (between V1 and V2)
Atorvastatin	Atorvastatin 10 mg
Pravastatin	Pravastatin 40 mg
Rosuvastatin	Rosuvastatin 5 mg

Measured Values

	Initial Phase	Atorvastatin	Pravastatin	Rosuvastatin
Number of Participants Analyzed	0	97	91	103
Compare the Percentage of Variation From Baseline Triglycerides Values and After 8 Weeks [units: percentage of triglycerides decrease] Mean (Standard Deviation)		-19.2 (25)	-6.1 (31.6)	-8.7 (37)

7. Secondary Outcome Measure:

Measure Title	Compare the Percentage of Variation From Baseline Apolipoprotein B/Apolipoprotein A1 Ratio and After 8 Weeks of Treatment
Measure Description	To Compare the percentage of variation from baseline Apolipoprotein B/Apolipoprotein A1 ratio and after 8 weeks of treatment. As the recruitment target was not reached at the date initially planned, and in view of the recruitment difficulties, AstraZeneca decided not to extend the patient recruitment period and to perform only a descriptive analysis of the data
Time Frame	baseline and after 8 weeks of treatment

Safety Issue?	No

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
Initial Phase	Initial phase (between V1 and V2)
Atorvastatin	Atorvastatin 10 mg
Pravastatin	Pravastatin 40 mg
Rosuvastatin	Rosuvastatin 5 mg

Measured Values

	Initial Phase	Atorvastatin	Pravastatin	Rosuvastatin
Number of Participants Analyzed	0	97	91	103
Compare the Percentage of Variation From Baseline Apolipoprotein B/Apolipoprotein A1 Ratio and After 8 Weeks of Treatment [units: percent. Apolipoprotein B/A1 decrease] Mean (Standard Deviation)		-30.9 (14.7)	-26 (13.5)	-31.9 (17)

8. Secondary Outcome Measure:

Measure Title	Compare the Percentage of Variation of C-reactive Protein (CRP)
Measure Description	To compare the percentage of variation of C-reactive protein (CRP) taking baseline values as reference. As the recruitment target was not reached at the date initially planned, and in view of the recruitment difficulties, AstraZeneca decided not to extend the patient recruitment period and to perform only a descriptive analysis of the data
Time Frame	baseline and after 8 weeks of treatment
Safety Issue?	No

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
Initial Phase	Initial phase (between V1 and V2)
Atorvastatin	Atorvastatin 10 mg
Pravastatin	Pravastatin 40 mg
Rosuvastatin	Rosuvastatin 5 mg

Measured Values

	Initial Phase	Atorvastatin	Pravastatin	Rosuvastatin
Number of Participants Analyzed	0	97	91	103
Compare the Percentage of Variation of C-reactive Protein (CRP) [units: percent of variation of C-reactive prot.] Mean (Standard Deviation)		37.3 (187.4)	33.1 (184.2)	15.2 (104.9)

9. Secondary Outcome Measure:

Measure Title	Compare the Percentage of Variation of Phospholipase A2 (PLA2)
Measure Description	To Compare the percentage of variation of phospholipase A2 (PLA2) taking baseline value as a reference. As the recruitment target was not reached at the date initially planned, and view of the recruitment difficulties, AstraZeneca decided not to extend the patient recruitment period and to perform only a descriptive analysis of the data
Time Frame	from baseline and after 8 weeks of treatment
Safety Issue?	No

Analysis Population Description

[Not Specified]

Reporting Groups

	Description
Initial Phase	Initial phase (between V1 and V2)
Atorvastatin	Atorvastatin 10 mg
Pravastatin	Pravastatin 40 mg
Rosuvastatin	Rosuvastatin 5 mg

Measured Values

	Initial Phase	Atorvastatin	Pravastatin	Rosuvastatin
Number of Participants Analyzed	0	84	78	83
Compare the Percentage of Variation of Phospholipase A2 (PLA2) [units: percent of variation of phospholipase A2] Mean (Standard Deviation)		5.6 (46.4)	13 (73.6)	2.9 (24.2)

10. Secondary Outcome Measure:

Measure Title	Compare the Numbers of Patients Achieving the LDL-C Goal According to the National Cholesterol Education Program Adult Treatment Panel III (NCEP) ATP III) Guidelines for the Management of Dyslipidaemic Patients
Measure Description	To Compare numbers of patients achieving the LDL-C goal according to the National Cholesterol Education Program Adult Treatment Panel III (NCEP). As the recruitment target was not reached at the date initially planned, and in view of the recruitment difficulties, AstraZeneca decided not to extend the patient recruitment period and to perform only a descriptive analysis of the data. The percentage of patients achieving the NCEP-ATP III LDL-C goal. ATP III is categorized into 3 risk categories:(1) established CHD and CHD risk equivalents(2) multiple risk factors(3) zero to one (0–1) risk factor
Time Frame	from baseline and after 8 weeks of treatment
Safety Issue?	No

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
Initial Phase	Initial phase (between V1 and V2)
Atorvastatin	Atorvastatin 10 mg
Pravastatin	Pravastatin 40 mg
Rosuvastatin	Rosuvastatin 5 mg

Measured Values

	Initial Phase	Atorvastatin	Pravastatin	Rosuvastatin
Number of Participants Analyzed	0	97	91	103

	Initial Phase	Atorvastatin	Pravastatin	Rosuvastatin
Compare the Numbers of Patients Achieving the LDL-C Goal According to the National Cholesterol Education Program Adult Treatment Panel III (NCEP) ATP III) Guidelines for the Management of Dyslipidaemic Patients [units: Participants]		42	22	38

11. Secondary Outcome Measure:

Measure Title	Compare the Numbers of Patients Achieving the LDL-C Goal According to the European Atherosclerosis Society (EAS) Guidelines for the Management of Dyslipidaemic Patients
Measure Description	Not done. As the recruitment target was not reached at the date initially planned, and in view of the recruitment difficulties, AstraZeneca decided not to extend the patient recruitment period and to perform only a descriptive analysis of the data.
Time Frame	n/a
Safety Issue?	No

Outcome Measure Data Not Reported

12. Secondary Outcome Measure:

Measure Title	To Evaluate Clinical and Laboratory Safety
Measure Description	Serious Adverse Event and Adverse Event reported throughout the study
Time Frame	duration of study
Safety Issue?	No

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
Initial Phase	Initial phase (between V1 and V2)
Atorvastatin	Atorvastatin 10 mg
Pravastatin	Pravastatin 40 mg
Rosuvastatin	Rosuvastatin 5 mg

Measured Values

	Initial Phase	Atorvastatin	Pravastatin	Rosuvastatin
Number of Participants Analyzed	317	97	92	103
To Evaluate Clinical and Laboratory Safety [units: Adverse Events]	8	9	8	5

Reported Adverse Events

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

Reporting Groups

	Description
Initial Phase	Initial phase (between V1 and V2)
Atorvastatin	Atorvastatin 10 mg
Pravastatin	Pravastatin 40 mg
Rosuvastatin	Rosuvastatin 5 mg

Serious Adverse Events

	Initial Phase	Atorvastatin	Pravastatin	Rosuvastatin
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	2/317 (0.63%)	4/97 (4.12%)	1/92 (1.09%)	0/103 (0%)
Gastrointestinal disorders				
Vliolent abdominal pain [A] †	0/317 (0%)	1/97 (1.03%)	0/92 (0%)	0/103 (0%)
Musculoskeletal and connective tissue disorders				
Coxarthrosisaggravation [A] †	1/317 (0.32%)	0/97 (0%)	0/92 (0%)	0/103 (0%)
Worsening of gonalgia [A] †	0/317 (0%)	1/97 (1.03%)	0/92 (0%)	0/103 (0%)
Nervous system disorders				

	Initial Phase	Atorvastatin	Pravastatin	Rosuvastatin
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Carotid thrombosis [A] †	1/317 (0.32%)	0/97 (0%)	0/92 (0%)	0/103 (0%)
Left Lumbar Cruralgia [A] †	0/317 (0%)	1/97 (1.03%)	0/92 (0%)	0/103 (0%)
Morton syndrome [A] †	0/317 (0%)	1/97 (1.03%)	0/92 (0%)	0/103 (0%)
Reproductive system and breast disorders				
Benign prostatic nodular hyperplasia [A] †	0/317 (0%)	0/97 (0%)	1/92 (1.09%)	0/103 (0%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA 10.0

Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 0%

	Initial Phase	Atorvastatin	Pravastatin	Rosuvastatin
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	6/317 (1.89%)	5/97 (5.15%)	7/92 (7.61%)	5/103 (4.85%)
Cardiac disorders				
Tachycardia [A] †	0/317 (0%)	0/97 (0%)	0/92 (0%)	1/103 (0.97%)
Eye disorders				
visual impairment [A] †	0/317 (0%)	0/97 (0%)	0/92 (0%)	1/103 (0.97%)
Gastrointestinal disorders				
Diarrhea [A] †	0/317 (0%)	0/97 (0%)	0/92 (0%)	1/103 (0.97%)
Dyspepsia [A] †	0/317 (0%)	0/97 (0%)	2/92 (2.17%)	0/103 (0%)
Nausea [A] †	0/317 (0%)	0/97 (0%)	3/92 (3.26%)	0/103 (0%)
Vomiting [A] †	0/317 (0%)	0/97 (0%)	2/92 (2.17%)	0/103 (0%)
abdominal distension [A] †	0/317 (0%)	0/97 (0%)	1/92 (1.09%)	0/103 (0%)
abdominal pain [A] †	0/317 (0%)	1/97 (1.03%)	0/92 (0%)	0/103 (0%)
gingival hypoplasia [A] †	0/317 (0%)	1/97 (1.03%)	0/92 (0%)	0/103 (0%)

	Initial Phase	Atorvastatin	Pravastatin	Rosuvastatin
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Immune system disorders				
hypersensitivity [A] †	1/317 (0.32%)	0/97 (0%)	0/92 (0%)	0/103 (0%)
Infections and infestations				
Laryngitis [A] †	1/317 (0.32%)	0/97 (0%)	0/92 (0%)	0/103 (0%)
Otitis externa [A] †	1/317 (0.32%)	0/97 (0%)	0/92 (0%)	0/103 (0%)
Rhinitis [A] †	1/317 (0.32%)	0/97 (0%)	0/92 (0%)	0/103 (0%)
fungal infection [A] †	0/317 (0%)	0/97 (0%)	1/92 (1.09%)	0/103 (0%)
lung infection [A] †	0/317 (0%)	0/97 (0%)	1/92 (1.09%)	0/103 (0%)
sinusitis [A] †	1/317 (0.32%)	0/97 (0%)	0/92 (0%)	0/103 (0%)
vaginal infection [A] †	0/317 (0%)	0/97 (0%)	0/92 (0%)	1/103 (0.97%)
Injury, poisoning and procedural complications				
Joint Injury [A] †	1/317 (0.32%)	0/97 (0%)	0/92 (0%)	0/103 (0%)
Metabolism and nutrition disorders				
Gout [A] †	0/317 (0%)	1/97 (1.03%)	0/92 (0%)	0/103 (0%)
Musculoskeletal and connective tissue disorders				
Arthralgia [A] †	0/317 (0%)	1/97 (1.03%)	1/92 (1.09%)	0/103 (0%)
Back Pain [A] †	1/317 (0.32%)	0/97 (0%)	1/92 (1.09%)	0/103 (0%)
Muscle Spasms [A] †	0/317 (0%)	0/97 (0%)	1/92 (1.09%)	2/103 (1.94%)
Myalgia [A] †	0/317 (0%)	1/97 (1.03%)	0/92 (0%)	2/103 (1.94%)
Osteoarthritis [A] †	0/317 (0%)	0/97 (0%)	1/92 (1.09%)	0/103 (0%)
knee arthroplasty joint prosthesis user [A] †	1/317 (0.32%)	0/97 (0%)	0/92 (0%)	0/103 (0%)
Nervous system disorders				
Headache [A] †	1/317 (0.32%)	0/97 (0%)	0/92 (0%)	0/103 (0%)

	Initial Phase	Atorvastatin	Pravastatin	Rosuvastatin
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Morton's neuralgia [A] †	1/317 (0.32%)	0/97 (0%)	0/92 (0%)	0/103 (0%)
Sciatica [A] †	1/317 (0.32%)	0/97 (0%)	0/92 (0%)	0/103 (0%)
Reproductive system and breast disorders				
benign prostatic hyperplasia [A] †	0/317 (0%)	0/97 (0%)	1/92 (1.09%)	0/103 (0%)
Respiratory, thoracic and mediastinal disorders				
Ear Infection [A] †	1/317 (0.32%)	0/97 (0%)	0/92 (0%)	0/103 (0%)
Laryngitis [A] †	1/317 (0.32%)	0/97 (0%)	0/92 (0%)	0/103 (0%)
Skin and subcutaneous tissue disorders				
Rash [A] †	0/317 (0%)	0/97 (0%)	0/92 (0%)	1/103 (0.97%)
erythema [A] †	0/317 (0%)	0/97 (0%)	0/92 (0%)	1/103 (0.97%)
skin discolouration [A] †	0/317 (0%)	0/97 (0%)	1/92 (1.09%)	0/103 (0%)
Vascular disorders				
deep vein thrombosis [A] †	0/317 (0%)	1/97 (1.03%)	0/92 (0%)	0/103 (0%)
venous insufficiency [A] †	0/317 (0%)	1/97 (1.03%)	0/92 (0%)	0/103 (0%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA 10.0

Limitations and Caveats

As the recruitment target was not reached at the date initially planned, and in view of the recruitment difficulties, AstraZeneca decided not to extend the patient recruitment period and to perform only a descriptive analysis of the data.

More Information

Certain Agreements:

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

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

If the PI wants to discuss or publish results after the trial is completed he must obtain writing authorization from AstraZeneca

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