ClinicalTrials.gov Protocol and Results Registration System (PRS) Receipt
Release Date: 05/11/2011

ClinicalTrials.gov ID: NCT00525824

Study Identification

Unique Protocol ID:	D356FC00003
Brief Title:	12-week Open-label, Phase IIIb Comparing Efficacy and Safety of Rosuvastatin (CRESTOR™) in Combination With Ezetimibe (GRAVITY)
Official Title:	A 12-week Open-label, Randomised, Parallel-group, Multicentre, Phase IIIb Study to Compare the Efficacy and Safety of Rosuvastatin (CRESTOR™) in Combination With Ezetimibe and Simvastatin in Patients With Hypercholesterolaemia and CHD
Secondary IDs:	

Study Status

Record Verification:	May 2011
Overall Status:	Completed
Study Start:	August 2007
Primary Completion:	September 2008 [Actual]
Study Completion:	September 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?:	Yes
IND/IDE Information:	Grantor: CDER IND/IDE Number: 56,385 Serial Number: 614 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

Study Description

Brief Summary:	The purpose of this study is to determine whether treatment of Rosuvastatin (CRESTOR™) or Simvastatin given as monotherapy or given in combination with Ezetimibe, will lower the Low Density Lipoprotein Cholesterol (LDL-C) in patients with Hypercholesterolaemia and Coronary Heart Disease (CHD) or a CHD Risk Equivalent, Atherosclerosis or a 10-year CHD Risk of >20%
Detailed Description:	

Conditions

Conditions:	Hypercholesterolemia Coronary Heart Disease Atherosclerosis
Keywords:	Hypercholesterolaemia Coronary Heart Disease (CHD) Atherosclerosis

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment

Study Phase:	Phase 3
Intervention Model:	Parallel Assignment
Number of Arms:	
Masking:	Open Label
Allocation:	Randomized
Endpoint Classification:	Efficacy Study
Enrollment:	1743 [Actual]

Arms and Interventions

Intervention Details:

Drug: Rosuvastatin (Crestor)
10mg and 20 mg

Drug: Ezetimibe
10 mg

Drug: Simvastatin
40mg and 80 mg

Outcome Measures

[See Results Section.]

Eligibility

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

- Patients with with hypercholesterolaemia and CHD or a CHD risk equivalent, clinical evidence of atherosclerosis or a Framingham 10-year CHD risk score of >20
- Patients will need to sign an informed consent before any visit procedures can be performed, including procedures for the optional genetic research and biomarker studies.
- Patients must be 18 years or older and will be asked to stop taking any current cholesterol-lowering medications. Dietary counselling will be provided which will include an overview of the Therapeutic Lifestyle Change (TLC) diet the patients will be asked to follow

Exclusion Criteria:

- Use of lipid lowering drugs and other prohibited concomitant medications. History of statin-induced myopathy, or serious hypersensitivity reaction to other HMG-CoA reductase inhibitors (statins), including rosuvastatin, simvastatin and/or a history of hypersensitivity to any components of ezetimibe.
- Patients considered to be unstable by their physician after the following events:

a myocardial infarction, recent episode of unstable angina, myocardial revascularisation [percutaneous transluminal coronary angioplasty (PTCA), coronary artery bypass graft (CABG) surgery or another revascularisation procedure] or a transient ischaemic attack (TIA) or stroke and patients awaiting a planned myocardial revascularisation

Contacts/Locations

Study Officials: Christie M Ballantyne, MD FACP FACC
Study Principal Investigator
Centre for Cardiovascular Disease Prevention

Margareta Grind, MD PhD FFPM
Study Chair
Medicine and Sciences AstraZeneca

Locations: Argentina
Research Site
Buenos Aires, Argentina

Brazil
Research Site
Sao Paulo, SP, Brazil

Chile
Research Site
Santiago, Chile

Colombia
Research Site
Brentwood, Colombia

Lithuania
Research Site
Brentwood, Lithuania

Netherlands
Research Site
Zwinderen, Netherlands

Peru
Research Site
Lima, San Isidro Lima, Peru

United States, Tennessee
Research Site
Brentwood, Tennessee, United States

Venezuela
Research Site
Brentwood, Venezuela

References

Citations:

Links:

Study Data/Documents:

Study Results

Participant Flow

Recruitment Details	Eight hundred thirty-three patients (with hypercholesterolaemia and CHD or CHD risk equivalent, atherosclerosis or a 10-year CHD risk of >20%) were randomized into the study, from 111 sites located in the United States (56), Peru (13), Netherlands (12), Colombia (8), Argentina (8), Brazil (6), Chile (4) and Lithuania (4).
Pre-Assignment Details	Patients underwent screening procedures (Week –6; Visit 1), and entered a 6-week dietary lead-in period. Those who fulfilled all eligibility criteria (Week –6; Visit 1) and had qualifying lipid values at Visit 2 were randomly allocated (1:1:1:1) to 1 of 4 treatments for a period of 12 weeks.

Reporting Groups

	Description
R10 to R10 + E10	Rosuvastatin 10 mg followed by Rosuvastatin 10 mg + Ezetimibe 10 mg
R20 to R20 + E10	Rosuvastatin 20 mg followed by Rosuvastatin 20 mg + Ezetimibe 10 mg
S40 to S40 + E10	Simvastatin 40 mg followed by Simvastatin 40 mg + Ezetimibe 10 mg
S80 to S80 + E10	Simvastatin 80 mg followed by Simvastatin 80 mg + Ezetimibe 10 mg

Overall Study

	R10 to R10 + E10	R20 to R20 + E10	S40 to S40 + E10	S80 to S80 + E10
Started	214 [1]	214 [1]	202 [1]	203 [1]
Completed	195	186	183	188
Not Completed	19	28	19	15
Adverse Event	7	11	6	7
Withdrawal by Subject	5	9	3	4
Lost to Follow-up	4	2	4	0
Incorrect enrolment/mis-randomisation	1	2	1	2
Severe non-compliance	0	1	1	1
Safety reasons	1	0	1	0
Other	1	3	3	1

[1] Randomized population

Baseline Characteristics

Reporting Groups

	Description
R10 to R10 + E10	Rosuvastatin 10 mg followed by Rosuvastatin 10 mg + Ezetimibe 10 mg
R20 to R20 + E10	Rosuvastatin 20 mg followed by Rosuvastatin 20 mg + Ezetimibe 10 mg
S40 to S40 + E10	Simvastatin 40 mg followed by Simvastatin 40 mg + Ezetimibe 10 mg
S80 to S80 + E10	Simvastatin 80 mg followed by Simvastatin 80 mg + Ezetimibe 10 mg

Baseline Measures

	R10 to R10 + E10	R20 to R20 + E10	S40 to S40 + E10	S80 to S80 + E10	Total
Number of Participants	214	214	202	203	833
Age, Continuous [units: years] Mean (Standard Deviation)	62.2 (10.14)	61.8 (9.93)	61.9 (9.37)	62.1 (9.17)	62.0 (9.66)

	R10 to R10 + E10	R20 to R20 + E10	S40 to S40 + E10	S80 to S80 + E10	Total
Gender, Male/Female [units: Participants]					
Female	91.0000	97.0000	97.0000	90.0000	375.0
Male	123.0000	117.0000	105.0000	113.0000	458.0

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Percent Change From Baseline in Low-density Lipoprotein Cholesterol (LDL-C) After 6 Weeks Combination Treatment
Measure Description	Percent change in LDL-C = (Combination treatment value - Baseline value)/Baseline value*100
Time Frame	Mean of Weeks 4 and 6 on combination therapy (Last observation carried forward)
Safety Issue?	No

Analysis Population Description

[Not Specified]

Reporting Groups

	Description
R10 to R10 + E10	Rosuvastatin 10 mg followed by Rosuvastatin 10 mg + Ezetimibe 10 mg
R20 to R20 + E10	Rosuvastatin 20 mg followed by Rosuvastatin 20 mg + Ezetimibe 10 mg
S40 to S40 + E10	Simvastatin 40 mg followed by Simvastatin 40 mg + Ezetimibe 10 mg
S80 to S80 + E10	Simvastatin 80 mg followed by Simvastatin 80 mg + Ezetimibe 10 mg

Measured Values

	R10 to R10 + E10	R20 to R20 + E10	S40 to S40 + E10	S80 to S80 + E10
Number of Participants Analyzed	210	204	199	201
Percent Change From Baseline in Low-density Lipoprotein Cholesterol (LDL-C) After 6 Weeks Combination Treatment [units: Percentage] Mean (Standard Deviation)	-59.7200 (14.1660)	-63.4800 (16.6970)	-55.2200 (15.7500)	-57.4200 (20.4660)

2. Secondary Outcome Measure:

Measure Title	Percent Change in High-density Lipoprotein Cholesterol (HDL-C) After 6 Weeks Combination Treatment
Measure Description	Percent change in HDL-C = (Combination treatment value - Baseline value)/Baseline value*100
Time Frame	Mean of Weeks 4 and 6 on combination therapy (Last observation carried forward)
Safety Issue?	No

Analysis Population Description

[Not Specified]

Reporting Groups

	Description
R10 to R10 + E10	Rosuvastatin 10 mg followed by Rosuvastatin 10 mg + Ezetimibe 10 mg
R20 to R20 + E10	Rosuvastatin 20 mg followed by Rosuvastatin 20 mg + Ezetimibe 10 mg
S40 to S40 + E10	Simvastatin 40 mg followed by Simvastatin 40 mg + Ezetimibe 10 mg
S80 to S80 + E10	Simvastatin 80 mg followed by Simvastatin 80 mg + Ezetimibe 10 mg

Measured Values

	R10 to R10 + E10	R20 to R20 + E10	S40 to S40 + E10	S80 to S80 + E10
Number of Participants Analyzed	210	204	199	201
Percent Change in High-density Lipoprotein Cholesterol (HDL-C) After 6 Weeks Combination Treatment [units: Percentage] Mean (Standard Deviation)	6.4100 (13.9340)	7.4600 (16.3510)	3.9200 (12.6830)	4.3400 (12.6430)

3. Secondary Outcome Measure:

Measure Title	Percent Change in Total Cholesterol (TC) After 6 Weeks Combination Treatment
Measure Description	Percent change in TC = (Combination treatment value - Baseline value)/Baseline value*100
Time Frame	Mean of Weeks 4 and 6 on combination therapy (Last observation carried forward)
Safety Issue?	No

Analysis Population Description

[Not Specified]

Reporting Groups

	Description
R10 to R10 + E10	Rosuvastatin 10 mg followed by Rosuvastatin 10 mg + Ezetimibe 10 mg
R20 to R20 + E10	Rosuvastatin 20 mg followed by Rosuvastatin 20 mg + Ezetimibe 10 mg
S40 to S40 + E10	Simvastatin 40 mg followed by Simvastatin 40 mg + Ezetimibe 10 mg
S80 to S80 + E10	Simvastatin 80 mg followed by Simvastatin 80 mg + Ezetimibe 10 mg

Measured Values

	R10 to R10 + E10	R20 to R20 + E10	S40 to S40 + E10	S80 to S80 + E10
Number of Participants Analyzed	210	204	199	201
Percent Change in Total Cholesterol (TC) After 6 Weeks Combination Treatment [units: Percentage] Mean (Standard Deviation)	-43.0000 (11.2080)	-46.6300 (12.8180)	-39.5600 (12.6640)	-41.7100 (15.1500)

4. Secondary Outcome Measure:

Measure Title	Percent Change in Triglycerides (TG) After 6 Weeks Combination Treatment
Measure Description	Percent change in TG = (Combination treatment value - Baseline value)/Baseline value*100
Time Frame	Mean of Weeks 4 and 6 on combination therapy (Last observation carried forward)
Safety Issue?	No

Analysis Population Description

[Not Specified]

Reporting Groups

	Description
R10 to R10 + E10	Rosuvastatin 10 mg followed by Rosuvastatin 10 mg + Ezetimibe 10 mg
R20 to R20 + E10	Rosuvastatin 20 mg followed by Rosuvastatin 20 mg + Ezetimibe 10 mg
S40 to S40 + E10	Simvastatin 40 mg followed by Simvastatin 40 mg + Ezetimibe 10 mg
S80 to S80 + E10	Simvastatin 80 mg followed by Simvastatin 80 mg + Ezetimibe 10 mg

Measured Values

	R10 to R10 + E10	R20 to R20 + E10	S40 to S40 + E10	S80 to S80 + E10
Number of Participants Analyzed	210	204	199	201
Percent Change in Triglycerides (TG) After 6 Weeks Combination Treatment [units: Percentage] Mean (Standard Deviation)	-28.8500 (23.7090)	-35.0000 (23.9710)	-22.9500 (28.1390)	-25.8200 (26.6190)

5. Secondary Outcome Measure:

Measure Title	Percent Change in Non-high-density Lipoprotein Cholesterol (nonHDL-C) After 6 Weeks Combination Treatment
Measure Description	Percent change in nonHDL-C = (Combination treatment value - Baseline value)/Baseline value*100
Time Frame	Mean of Weeks 4 and 6 on combination therapy (Last observation carried forward)
Safety Issue?	No

Analysis Population Description

[Not Specified]

Reporting Groups

	Description
R10 to R10 + E10	Rosuvastatin 10 mg followed by Rosuvastatin 10 mg + Ezetimibe 10 mg
R20 to R20 + E10	Rosuvastatin 20 mg followed by Rosuvastatin 20 mg + Ezetimibe 10 mg
S40 to S40 + E10	Simvastatin 40 mg followed by Simvastatin 40 mg + Ezetimibe 10 mg
S80 to S80 + E10	Simvastatin 80 mg followed by Simvastatin 80 mg + Ezetimibe 10 mg

Measured Values

	R10 to R10 + E10	R20 to R20 + E10	S40 to S40 + E10	S80 to S80 + E10
Number of Participants Analyzed	210	204	199	201
Percent Change in Non-high-density Lipoprotein Cholesterol (nonHDL-C) After 6 Weeks Combination Treatment [units: Percentage] Mean (Standard Deviation)	-54.6500 (13.6770)	-58.9100 (14.9320)	-49.9300 (14.7380)	-52.3700 (18.4290)

6. Secondary Outcome Measure:

Measure Title	Percent Change in Apolipoprotein B (ApoB) After 6 Weeks Combination Treatment
Measure Description	Percent change in ApoB = (Combination treatment value - Baseline value)/Baseline value*100
Time Frame	Mean of Weeks 4 and 6 on combination therapy (Last observation carried forward)
Safety Issue?	No

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
R10 to R10 + E10	Rosuvastatin 10 mg followed by Rosuvastatin 10 mg + Ezetimibe 10 mg
R20 to R20 + E10	Rosuvastatin 20 mg followed by Rosuvastatin 20 mg + Ezetimibe 10 mg
S40 to S40 + E10	Simvastatin 40 mg followed by Simvastatin 40 mg + Ezetimibe 10 mg
S80 to S80 + E10	Simvastatin 80 mg followed by Simvastatin 80 mg + Ezetimibe 10 mg

Measured Values

	R10 to R10 + E10	R20 to R20 + E10	S40 to S40 + E10	S80 to S80 + E10
Number of Participants Analyzed	206	199	194	199
Percent Change in Apolipoprotein B (ApoB) After 6 Weeks Combination Treatment [units: Percentage] Mean (Standard Deviation)	-46.1100 (12.6280)	-49.5000 (13.8210)	-41.9500 (14.7500)	-44.1700 (17.1790)

7. Secondary Outcome Measure:

Measure Title	Percent Change in Apolipoprotein A1 (ApoA-1) After 6 Weeks Combination Treatment
Measure Description	Percent change in ApoA-1 = (Combination treatment value - Baseline value)/Baseline value*100
Time Frame	Mean of Weeks 4 and 6 on combination therapy (Last observation carried forward)
Safety Issue?	No

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
R10 to R10 + E10	Rosuvastatin 10 mg followed by Rosuvastatin 10 mg + Ezetimibe 10 mg
R20 to R20 + E10	Rosuvastatin 20 mg followed by Rosuvastatin 20 mg + Ezetimibe 10 mg
S40 to S40 + E10	Simvastatin 40 mg followed by Simvastatin 40 mg + Ezetimibe 10 mg
S80 to S80 + E10	Simvastatin 80 mg followed by Simvastatin 80 mg + Ezetimibe 10 mg

Measured Values

	R10 to R10 + E10	R20 to R20 + E10	S40 to S40 + E10	S80 to S80 + E10
Number of Participants Analyzed	206	199	194	199
Percent Change in Apolipoprotein A1 (ApoA-1) After 6 Weeks Combination Treatment [units: Percentage] Mean (Standard Deviation)	3.8100 (13.0420)	2.6800 (11.5020)	1.4900 (9.6830)	2.1300 (10.7410)

8. Secondary Outcome Measure:

Measure Title	Percent Change in TC/HDL-C After 6 Weeks Combination Treatment
Measure Description	Percent change in TC/HDL-C = (Combination treatment value - Baseline value)/Baseline value*100
Time Frame	Mean of Weeks 4 and 6 on combination therapy (Last observation carried forward)
Safety Issue?	No

Analysis Population Description

[Not Specified]

Reporting Groups

	Description
R10 to R10 + E10	Rosuvastatin 10 mg followed by Rosuvastatin 10 mg + Ezetimibe 10 mg
R20 to R20 + E10	Rosuvastatin 20 mg followed by Rosuvastatin 20 mg + Ezetimibe 10 mg
S40 to S40 + E10	Simvastatin 40 mg followed by Simvastatin 40 mg + Ezetimibe 10 mg
S80 to S80 + E10	Simvastatin 80 mg followed by Simvastatin 80 mg + Ezetimibe 10 mg

Measured Values

	R10 to R10 + E10	R20 to R20 + E10	S40 to S40 + E10	S80 to S80 + E10
Number of Participants Analyzed	210	204	199	201
Percent Change in TC/HDL-C After 6 Weeks Combination Treatment [units: Percentage] Mean (Standard Deviation)	-45.5200 (13.2280)	-49.4600 (13.5750)	-41.2700 (13.0210)	-43.4500 (16.3430)

9. Secondary Outcome Measure:

Measure Title	Percent Change in LDL-C/HDL-C After 6 Weeks Combination Treatment
Measure Description	Percent change in LDL-C/HDL-C = (Combination treatment value - Baseline value)/Baseline value*100
Time Frame	Mean of Weeks 4 and 6 on combination therapy (Last observation carried forward)
Safety Issue?	No

Analysis Population Description

[Not Specified]

Reporting Groups

	Description
R10 to R10 + E10	Rosuvastatin 10 mg followed by Rosuvastatin 10 mg + Ezetimibe 10 mg
R20 to R20 + E10	Rosuvastatin 20 mg followed by Rosuvastatin 20 mg + Ezetimibe 10 mg
S40 to S40 + E10	Simvastatin 40 mg followed by Simvastatin 40 mg + Ezetimibe 10 mg
S80 to S80 + E10	Simvastatin 80 mg followed by Simvastatin 80 mg + Ezetimibe 10 mg

Measured Values

	R10 to R10 + E10	R20 to R20 + E10	S40 to S40 + E10	S80 to S80 + E10
Number of Participants Analyzed	210	204	199	201
Percent Change in LDL-C/HDL-C After 6 Weeks Combination Treatment [units: Percentage] Mean (Standard Deviation)	-61.4700 (15.5470)	-65.2500 (16.6800)	-57.1300 (14.7770)	-58.6600 (21.1300)

10. Secondary Outcome Measure:

Measure Title	Percent Change in Non-HDL-C/HDL-C After 6 Weeks Combination Treatment
Measure Description	Percent change in non-HDL-C/HDL-C = (Combination treatment value - Baseline value)/Baseline value*100
Time Frame	Mean of Weeks 4 and 6 on combination therapy (Last observation carried forward)
Safety Issue?	No

Analysis Population Description

[Not Specified]

Reporting Groups

	Description
R10 to R10 + E10	Rosuvastatin 10 mg followed by Rosuvastatin 10 mg + Ezetimibe 10 mg
R20 to R20 + E10	Rosuvastatin 20 mg followed by Rosuvastatin 20 mg + Ezetimibe 10 mg
S40 to S40 + E10	Simvastatin 40 mg followed by Simvastatin 40 mg + Ezetimibe 10 mg
S80 to S80 + E10	Simvastatin 80 mg followed by Simvastatin 80 mg + Ezetimibe 10 mg

Measured Values

	R10 to R10 + E10	R20 to R20 + E10	S40 to S40 + E10	S80 to S80 + E10
Number of Participants Analyzed	210	204	199	201
Percent Change in Non-HDL-C/HDL-C After 6 Weeks Combination Treatment [units: Percentage] Mean (Standard Deviation)	-56.4200 (15.4150)	-60.8900 (15.5030)	-51.1100 (15.3800)	-53.5100 (20.2230)

11. Secondary Outcome Measure:

Measure Title	Percent Change in ApoB/ApoA-1 After 6 Weeks Combination Treatment
Measure Description	Percent change in ApoB/ApoA-1 = (Combination treatment value - Baseline value)/Baseline value*100
Time Frame	Mean of Weeks 4 and 6 on combination therapy (Last observation carried forward)
Safety Issue?	No

Analysis Population Description

[Not Specified]

Reporting Groups

	Description
R10 to R10 + E10	Rosuvastatin 10 mg followed by Rosuvastatin 10 mg + Ezetimibe 10 mg
R20 to R20 + E10	Rosuvastatin 20 mg followed by Rosuvastatin 20 mg + Ezetimibe 10 mg
S40 to S40 + E10	Simvastatin 40 mg followed by Simvastatin 40 mg + Ezetimibe 10 mg
S80 to S80 + E10	Simvastatin 80 mg followed by Simvastatin 80 mg + Ezetimibe 10 mg

Measured Values

	R10 to R10 + E10	R20 to R20 + E10	S40 to S40 + E10	S80 to S80 + E10
Number of Participants Analyzed	206	199	194	199
Percent Change in ApoB/ApoA-1 After 6 Weeks Combination Treatment [units: Percentage] Mean (Standard Deviation)	-47.3900 (13.8690)	-50.2400 (14.2570)	-42.5400 (14.2480)	-44.7600 (17.8420)

12. Secondary Outcome Measure:

Measure Title	Percent Change in High-sensitivity C-reactive Protein (Hs-CRP) After 6 Weeks Combination Treatment
Measure Description	Percent change in hs-CRP = (Combination treatment value - Baseline value)/Baseline value*100
Time Frame	Mean of Weeks 4 and 6 on combination therapy (Last observation carried forward)
Safety Issue?	No

Analysis Population Description

[Not Specified]

Reporting Groups

	Description
R10 to R10 + E10	Rosuvastatin 10 mg followed by Rosuvastatin 10 mg + Ezetimibe 10 mg
R20 to R20 + E10	Rosuvastatin 20 mg followed by Rosuvastatin 20 mg + Ezetimibe 10 mg
S40 to S40 + E10	Simvastatin 40 mg followed by Simvastatin 40 mg + Ezetimibe 10 mg
S80 to S80 + E10	Simvastatin 80 mg followed by Simvastatin 80 mg + Ezetimibe 10 mg

Measured Values

	R10 to R10 + E10	R20 to R20 + E10	S40 to S40 + E10	S80 to S80 + E10
Number of Participants Analyzed	207	202	197	199
Percent Change in High-sensitivity C-reactive Protein (Hs-CRP) After 6 Weeks Combination Treatment [units: Percentage] Mean (Full Range)	107.1200 (-99.0 to 20295.0)	-9.5300 (-97.9 to 2368.3)	15.0300 (-91.5 to 1611.4)	0.4200 (-94.9 to 1270.4)

13. Secondary Outcome Measure:

Measure Title	Percent Change in LDL-C After 6 Weeks Monotherapy
Measure Description	Percent change in LDL-C = (Monotherapy treatment value - Baseline value)/Baseline value*100
Time Frame	Mean of Weeks 4 and 6 on monotherapy (Last observation carried forward)
Safety Issue?	No

Analysis Population Description

[Not Specified]

Reporting Groups

	Description
R10 to R10 + E10	Rosuvastatin 10 mg followed by Rosuvastatin 10 mg + Ezetimibe 10 mg
R20 to R20 + E10	Rosuvastatin 20 mg followed by Rosuvastatin 20 mg + Ezetimibe 10 mg
S40 to S40 + E10	Simvastatin 40 mg followed by Simvastatin 40 mg + Ezetimibe 10 mg
S80 to S80 + E10	Simvastatin 80 mg followed by Simvastatin 80 mg + Ezetimibe 10 mg

Measured Values

	R10 to R10 + E10	R20 to R20 + E10	S40 to S40 + E10	S80 to S80 + E10
Number of Participants Analyzed	206	199	197	200
Percent Change in LDL-C After 6 Weeks Monotherapy [units: Percentage] Mean (Standard Deviation)	-46.4900 (13.1080)	-53.5900 (10.5030)	-40.8600 (12.4130)	-46.3500 (16.1880)

Reported Adverse Events

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

Reporting Groups

	Description
Rosuvastatin 10 mg	Rosuvastatin 10 mg Monotherapy arm
Rosuvastatin 20 mg	Rosuvastatin 20 mg Monotherapy arm
Simvastatin 40 mg	Simvastatin 40 mg Monotherapy arm
Simvastatin 80 mg	Simvastatin 80 mg Monotherapy arm
Rosu 10 mg + Eze 10 mg	Rosuvastatin 10 mg + Ezetimibe 10 mg
Rosu 20 mg + Eze 10 mg	Rosuvastatin 20 mg + Ezetimibe 10 mg
Simva 40 mg + Eze 10 mg	Simvastatin 40 mg + Ezetimibe 10 mg
Simva 80 mg + Eze 10 mg	Simvastatin 80 mg + Ezetimibe 10 mg

Serious Adverse Events

	Rosuvastatin 10 mg	Rosuvastatin 20 mg	Simvastatin 40 mg	Simvastatin 80 mg	Rosu 10 mg + Eze 10 mg	Rosu 20 mg + Eze 10 mg
	Affected/ At Risk (%)	Affected/ At Risk (%)	Affected/ At Risk (%)	Affected/ At Risk (%)	Affected/ At Risk (%)	Affected/ At Risk (%)
Total	3/	5/	1/	3/	4/	1/
Blood and lymphatic system disorders						
Anaemia [A] †	0/213 (0%)	0/212 (0%)	0/199 (0%)	0/203 (0%)	0/200 (0%)	0/191 (0%)
Cardiac disorders						
Acute myocardial infarction [A] †	0/213 (0%)	1/212 (0.47%)	0/199 (0%)	0/203 (0%)	0/200 (0%)	0/191 (0%)
Angina pectoris [A] †	1/213 (0.47%)	0/212 (0%)	0/199 (0%)	0/203 (0%)	1/200 (0.5%)	0/191 (0%)
Angina unstable [A] †	0/213 (0%)	0/212 (0%)	0/199 (0%)	0/203 (0%)	2/200 (1%)	0/191 (0%)
Cardiac failure [A] †	0/213 (0%)	1/212 (0.47%)	0/199 (0%)	0/203 (0%)	0/200 (0%)	0/191 (0%)
Myocardial ischaemia [A] †	0/213 (0%)	0/212 (0%)	0/199 (0%)	0/203 (0%)	0/200 (0%)	0/191 (0%)

	Rosuvastatin 10 mg	Rosuvastatin 20 mg	Simvastatin 40 mg	Simvastatin 80 mg	Rosu 10 mg + Eze 10 mg	Rosu 20 mg + Eze 10 mg
	Affected/ At Risk (%)	Affected/ At Risk (%)	Affected/ At Risk (%)	Affected/ At Risk (%)	Affected/ At Risk (%)	Affected/ At Risk (%)
Ventricular extrasystoles [A] †	0/213 (0%)	1/212 (0.47%)	0/199 (0%)	0/203 (0%)	0/200 (0%)	0/191 (0%)
Hepatobiliary disorders						
Liver disorder [A] †	0/213 (0%)	0/212 (0%)	0/199 (0%)	1/203 (0.49%)	0/200 (0%)	0/191 (0%)
Infections and infestations						
Abdominal abscess [A] †	0/213 (0%)	0/212 (0%)	0/199 (0%)	0/203 (0%)	0/200 (0%)	0/191 (0%)
Diverticulitis [A] †	0/213 (0%)	0/212 (0%)	0/199 (0%)	0/203 (0%)	0/200 (0%)	0/191 (0%)
Pneumonia [A] †	1/213 (0.47%)	0/212 (0%)	0/199 (0%)	0/203 (0%)	0/200 (0%)	0/191 (0%)
Staphylococcal abscess [A] †	0/213 (0%)	0/212 (0%)	0/199 (0%)	0/203 (0%)	0/200 (0%)	1/191 (0.52%)
Injury, poisoning and procedural complications						
Fracture displacement [A] †	0/213 (0%)	0/212 (0%)	0/199 (0%)	0/203 (0%)	0/200 (0%)	0/191 (0%)
Metabolism and nutrition disorders						
Hypoglycaemia [A] †	0/213 (0%)	0/212 (0%)	0/199 (0%)	0/203 (0%)	0/200 (0%)	0/191 (0%)
Musculoskeletal and connective tissue disorders						
Myopathy [A] †	0/213 (0%)	0/212 (0%)	0/199 (0%)	1/203 (0.49%)	0/200 (0%)	0/191 (0%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Colon cancer [A] †	0/213 (0%)	0/212 (0%)	0/199 (0%)	0/203 (0%)	1/200 (0.5%)	0/191 (0%)
Non-Hodgkin's lymphoma [A] †	0/213 (0%)	0/212 (0%)	0/199 (0%)	0/203 (0%)	0/200 (0%)	0/191 (0%)
Thyroid cancer [A] †	0/213 (0%)	0/212 (0%)	0/199 (0%)	0/203 (0%)	0/200 (0%)	0/191 (0%)
Nervous system disorders						
Cerebral ischaemia [A] †	0/213 (0%)	0/212 (0%)	0/199 (0%)	1/203 (0.49%)	0/200 (0%)	0/191 (0%)
Cerebrovascular accident [A] †	0/213 (0%)	2/212 (0.94%)	0/199 (0%)	0/203 (0%)	0/200 (0%)	0/191 (0%)
Transient ischaemic attack [A] †	0/213 (0%)	0/212 (0%)	1/199 (0.5%)	0/203 (0%)	1/200 (0.5%)	0/191 (0%)

	Rosuvastatin 10 mg	Rosuvastatin 20 mg	Simvastatin 40 mg	Simvastatin 80 mg	Rosu 10 mg + Eze 10 mg	Rosu 20 mg + Eze 10 mg
	Affected/ At Risk (%)	Affected/ At Risk (%)	Affected/ At Risk (%)	Affected/ At Risk (%)	Affected/ At Risk (%)	Affected/ At Risk (%)
Psychiatric disorders						
Alcoholism [A] †	0/213 (0%)	0/212 (0%)	0/199 (0%)	1/203 (0.49%)	0/200 (0%)	0/191 (0%)
Respiratory, thoracic and mediastinal disorders						
Pulmonary embolism [A] †	1/213 (0.47%)	0/212 (0%)	0/199 (0%)	0/203 (0%)	0/200 (0%)	0/191 (0%)
Vascular disorders						
Arterial thrombosis limb [A] †	1/213 (0.47%)	0/212 (0%)	0/199 (0%)	0/203 (0%)	0/200 (0%)	0/191 (0%)

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

	Simva 40 mg + Eze 10 mg	Simva 80 mg + Eze 10 mg
	Affected/At Risk (%)	Affected/At Risk (%)
Total	7/	4/
Blood and lymphatic system disorders		
Anaemia [A] †	0/189 (0%)	1/192 (0.52%)
Cardiac disorders		
Acute myocardial infarction [A] †	0/189 (0%)	0/192 (0%)
Angina pectoris [A] †	0/189 (0%)	0/192 (0%)
Angina unstable [A] †	3/189 (1.59%)	0/192 (0%)
Cardiac failure [A] †	0/189 (0%)	0/192 (0%)
Myocardial ischaemia [A] †	1/189 (0.53%)	0/192 (0%)
Ventricular extrasystoles [A] †	0/189 (0%)	0/192 (0%)
Hepatobiliary disorders		
Liver disorder [A] †	0/189 (0%)	0/192 (0%)
Infections and infestations		

	Simva 40 mg + Eze 10 mg	Simva 80 mg + Eze 10 mg
	Affected/At Risk (%)	Affected/At Risk (%)
Abdominal abscess [A] †	0/189 (0%)	1/192 (0.52%)
Diverticulitis [A] †	0/189 (0%)	1/192 (0.52%)
Pneumonia [A] †	0/189 (0%)	0/192 (0%)
Staphylococcal abscess [A] †	0/189 (0%)	0/192 (0%)
Injury, poisoning and procedural complications		
Fracture displacement [A] †	1/189 (0.53%)	0/192 (0%)
Metabolism and nutrition disorders		
Hypoglycaemia [A] †	0/189 (0%)	1/192 (0.52%)
Musculoskeletal and connective tissue disorders		
Myopathy [A] †	0/189 (0%)	0/192 (0%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Colon cancer [A] †	0/189 (0%)	0/192 (0%)
Non-Hodgkin's lymphoma [A] †	1/189 (0.53%)	0/192 (0%)
Thyroid cancer [A] †	1/189 (0.53%)	0/192 (0%)
Nervous system disorders		
Cerebral ischaemia [A] †	0/189 (0%)	0/192 (0%)
Cerebrovascular accident [A] †	0/189 (0%)	0/192 (0%)
Transient ischaemic attack [A] †	0/189 (0%)	0/192 (0%)
Psychiatric disorders		
Alcoholism [A] †	0/189 (0%)	0/192 (0%)
Respiratory, thoracic and mediastinal disorders		
Pulmonary embolism [A] †	0/189 (0%)	0/192 (0%)
Vascular disorders		

	Simva 40 mg + Eze 10 mg	Simva 80 mg + Eze 10 mg
	Affected/At Risk (%)	Affected/At Risk (%)
Arterial thrombosis limb [A] †	0/189 (0%)	0/192 (0%)

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

Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 2%

	Rosuvastatin 10 mg	Rosuvastatin 20 mg	Simvastatin 40 mg	Simvastatin 80 mg	Rosu 10 mg + Eze 10 mg	Rosu 20 mg + Eze 10 mg
	Affected/ At Risk (%)	Affected/ At Risk (%)	Affected/ At Risk (%)	Affected/ At Risk (%)	Affected/ At Risk (%)	Affected/ At Risk (%)
Total	25/	31/	28/	26/	18/	23/
Gastrointestinal disorders						
Nausea [A] †	4/213 (1.88%)	5/212 (2.36%)	1/199 (0.5%)	1/203 (0.49%)	1/200 (0.5%)	3/191 (1.57%)
General disorders						
Oedema peripheral [A] †	0/213 (0%)	0/212 (0%)	0/199 (0%)	0/203 (0%)	1/200 (0.5%)	0/191 (0%)
Infections and infestations						
Bronchitis [A] †	1/213 (0.47%)	1/212 (0.47%)	4/199 (2.01%)	2/203 (0.99%)	3/200 (1.5%)	2/191 (1.05%)
Influenza [A] †	2/213 (0.94%)	1/212 (0.47%)	4/199 (2.01%)	1/203 (0.49%)	0/200 (0%)	4/191 (2.09%)
Nasopharyngitis [A] †	3/213 (1.41%)	3/212 (1.42%)	4/199 (2.01%)	3/203 (1.48%)	2/200 (1%)	5/191 (2.62%)
Upper respiratory tract infection [A] †	1/213 (0.47%)	1/212 (0.47%)	4/199 (2.01%)	3/203 (1.48%)	2/200 (1%)	1/191 (0.52%)
Musculoskeletal and connective tissue disorders						
Arthralgia [A] †	5/213 (2.35%)	4/212 (1.89%)	1/199 (0.5%)	4/203 (1.97%)	2/200 (1%)	0/191 (0%)
Muscle spasms [A] †	1/213 (0.47%)	2/212 (0.94%)	4/199 (2.01%)	1/203 (0.49%)	2/200 (1%)	1/191 (0.52%)
Myalgia [A] †	5/213 (2.35%)	10/212 (4.72%)	3/199 (1.51%)	7/203 (3.45%)	4/200 (2%)	5/191 (2.62%)
Nervous system disorders						
Dizziness [A] †	1/213 (0.47%)	5/212 (2.36%)	1/199 (0.5%)	2/203 (0.99%)	1/200 (0.5%)	2/191 (1.05%)

	Rosuvastatin 10 mg	Rosuvastatin 20 mg	Simvastatin 40 mg	Simvastatin 80 mg	Rosu 10 mg + Eze 10 mg	Rosu 20 mg + Eze 10 mg
	Affected/ At Risk (%)	Affected/ At Risk (%)	Affected/ At Risk (%)	Affected/ At Risk (%)	Affected/ At Risk (%)	Affected/ At Risk (%)
Headache [A] †	4/213 (1.88%)	4/212 (1.89%)	5/199 (2.51%)	4/203 (1.97%)	3/200 (1.5%)	1/191 (0.52%)

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

	Simva 40 mg + Eze 10 mg	Simva 80 mg + Eze 10 mg
	Affected/At Risk (%)	Affected/At Risk (%)
Total	24/	21/
Gastrointestinal disorders		
Nausea [A] †	2/189 (1.06%)	1/192 (0.52%)
General disorders		
Oedema peripheral [A] †	2/189 (1.06%)	4/192 (2.08%)
Infections and infestations		
Bronchitis [A] †	2/189 (1.06%)	1/192 (0.52%)
Influenza [A] †	3/189 (1.59%)	0/192 (0%)
Nasopharyngitis [A] †	2/189 (1.06%)	3/192 (1.56%)
Upper respiratory tract infection [A] †	3/189 (1.59%)	2/192 (1.04%)
Musculoskeletal and connective tissue disorders		
Arthralgia [A] †	1/189 (0.53%)	2/192 (1.04%)
Muscle spasms [A] †	3/189 (1.59%)	3/192 (1.56%)
Myalgia [A] †	4/189 (2.12%)	3/192 (1.56%)
Nervous system disorders		
Dizziness [A] †	3/189 (1.59%)	2/192 (1.04%)
Headache [A] †	1/189 (0.53%)	2/192 (1.04%)

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

Limitations and Caveats

[Not specified]

More Information

Certain Agreements:

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

There is NOT an agreement between the Principal Investigator and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

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