A Study to Assess the Cholesterol Lowering Effect of an Ezetimibe/Simvastatin Combination Tablet Compared to Another Cholesterol Lowering Drug in Patients With High Cholesterol and With High Cardiovascular Risk (0653A-809)(COMPLETED)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

Information provided by (Responsible Party):
Merck Sharp & Dohme Corp.

ClinicalTrials.gov Identifier:
NCT00479713

First received: May 24, 2007
Last updated: September 1, 2015
Last verified: September 2015
History of Changes

Full Text View | Tabular View | Study Results | Disclaimer | How to Read a Study Record

Purpose

This is a multicenter study to evaluate the safety and efficacy of ezetimibe/simvastatin versus rosuvastatin in participants with high cholesterol.

Condition	Intervention	Phase
Hypercholesterolemia	Drug: ezetimibe (+) simvastatin Drug: Comparator : rosuvastatin calcium Drug: Comparator: Placebo (unspecified)	Phase 3

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Safety/Efficacy Study
Intervention Model: Parallel Assignment
Masking: Double Blind (Subject, Investigator)
Primary Purpose: Treatment

Official Title: A Randomized, Double-Blind, Active-Controlled, Multicenter Study to Assess the LDL-C Lowering of Switching to a Combo Tab Ezetimibe/Simvastatin (10 mg/20 mg) Compared to Rosuvastatin 10 mg in Patients With Primary High Cholesterol and High Cardiovascular Risk Not Controlled With a Prior Statin Treatment

Resource links provided by NLM:

MedlinePlus related topics: Cholesterol

Drug Information available for: Simvastatin Rosuvastatin calcium Ezetimibe Rosuvastatin

U.S. FDA Resources

Further study details as provided by Merck Sharp & Dohme Corp.:

Primary Outcome Measures:

- Percent Change in Low Density Lipoprotein-Cholesterol (LDL-C) at Study Endpoint After Six Weeks of Treatment [Time Frame: Baseline and 6 weeks] [Designated as safety issue: No]

  Percent Change in LDL-C at study endpoint after six weeks of treatment is calculated as the difference between week 6 measure and baseline measure divided by baseline measure *100.

Secondary Outcome Measures:

- The Percentage of Participants Achieving Designated Low Density Lipoprotein-Cholesterol (LDL-C) Levels After 6 Weeks of Treatment [Time Frame: after 6 weeks of treatment] [Designated as safety issue: No]

  The percentage of participants who achieved a target LDL-C goal of < 100 mg/dL, of <70 mg/dL, and of <77 mg/dL at study endpoint after six weeks of treatment. The numerator is the number of participants in a treatment group who achieved a target LDL-C goal and the denominator is the total number of participants within that treatment group.

Other Outcome Measures:

- Percent Change From Baseline in Total Cholesterol [Time Frame: Baseline and 6 weeks] [Designated as safety issue: No]

  Percent change from baseline in total cholesterol at study endpoint after 6 weeks of treatment is calculated as the difference between week 6 measure and baseline measure divided by baseline measure *100.

- Percent Change From Baseline in Triglycerides. [Time Frame: Baseline and 6 weeks] [Designated as safety issue: No]

  Percent change from baseline in triglycerides at study endpoint after 6 weeks of treatment is calculated as the difference between week 6 measure and baseline measure divided by baseline measure *100.

- Percent Change From Baseline in High Density Lipoprotein-Cholesterol (HDL-C) [Time Frame: Baseline and 6 weeks] [Designated as safety issue: No]

  Percent change from baseline in HDL-C at study endpoint after 6 weeks of treatment is calculated as the difference between week 6 measure and baseline measure divided by baseline measure *100.

- Percent Change From Baseline in Non-High Density Lipoprotein-Cholesterol (Non-HDL-C) [Time Frame: Baseline and 6 weeks] [Designated as safety issue: No]

  Percent change from baseline in non HDL-C at study endpoint after 6 weeks of treatment is calculated as the difference between week 6 measure and baseline measure divided by baseline measure *100.

- Percent Change From Baseline in Low Density Lipoprotein-Cholesterol (LDL-C)/High Density Lipoprotein-Cholesterol (HDL-C) Ratio [Time Frame: Baseline and 6 weeks] [Designated as safety issue: No]

  Percent change from baseline in LDL-C/HDL-C ratio at study endpoint after 6 weeks of treatment is calculated as the difference between week 6 measure and baseline measure divided by baseline measure *100.

- Percent Change From Baseline in Total Cholesterol/High Density Lipoprotein-Cholesterol (HDL-C) Ratio [Time Frame: Baseline and 6 weeks] [Designated as safety issue: No]

  Percent change from baseline in total cholesterol/HDL-C ratio at study endpoint after 6 weeks of treatment is calculated as the difference between week 6 measure and baseline measure divided by baseline measure *100.

- Percent Change From Baseline in Apolipoprotein B [Time Frame: Baseline and 6 weeks] [Designated as safety issue: No]

  Percent change from baseline in apolipoprotein (Apo) B at study endpoint after 6 weeks of treatment is calculated as the difference between week 6 measure and baseline measure divided by baseline measure *100.

- Percent Change From Baseline in High-sensitivity C (Hs-C) Reactive Protein [Time Frame: Baseline and 6 weeks] [Designated as safety issue: No]

  Percent change from baseline in hs-C reactive protein at study endpoint after 6 weeks of treatment is calculated as the difference between week 6 measure and baseline measure divided by baseline measure *100.

Enrollment: 618

Study Start Date: February 2007
Study Completion Date: March 2008
Primary Completion Date: March 2008 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: 1 Arm 1: drug	Drug: ezetimibe (+) simvastatin ezetimibe/simvastatin 10/20mg. The treatment duration will be 6 weeks. Other Names: • MK0653A • Vytorin® Drug: Comparator: Placebo (unspecified) rosuvastatin 10mg Placebo. The treatment duration will be 6 weeks.
Active Comparator: 2 Arm 2: active comparator	Drug: Comparator : rosuvastatin calcium rosuvastatin 10mg. The treatment duration will be 6 weeks. Drug: Comparator: Placebo (unspecified) ezetimibe/simvastatin 10/20mg Placebo. The treatment duration will be 6 weeks.

Eligibility

Ages Eligible for Study: 18 Years to 79 Years
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- Participant is currently taking a statin medication for the treatment of high cholesterol
- Participant has an LDL-C level that is greater than or equal to 100 mg/dl and less than or equal to 190 mg/dl

Exclusion Criteria:

- Women who are pregnant or nursing, or women who intend to become pregnant
- Participant has any condition, situation, or is currently taking any medication that might pose a risk to the participant or interfere with participation in the study

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT00479713

Sponsors and Collaborators

Merck Sharp & Dohme Corp.

Investigators

Study Director: Medical Monitor Merck Sharp & Dohme Corp.

More Information

Additional Information:

(MedWatch - FDA maintained medical product safety Information) EXIT

(Merck: Patient & Caregiver U.S. Product Web Site)

Publications:

Farnier M, Averna M, Missault L, Vaverkova H, Viigimaa M, Massaad R, Vandormael K, Johnson-Levonas AO, Brudi P. Lipid-altering efficacy of ezetimibe/simvastatin 10/20 mg compared with rosuvastatin 10 mg in high-risk hypercholesterolaemic patients inadequately controlled with prior statin monotherapy - The IN-CROSS study. Int J Clin Pract. 2009 Apr;63(4):547-59. doi: 10.1111/j.1742-1241.2009.02022.x. Epub 2009 Feb 16.

Additional publications automatically indexed to this study by ClinicalTrials.gov Identifier (NCT Number):

Averna M, Missault L, Vaverkova H, Farnier M, Viigimaa M, Dong Q, Shah A, Johnson-Levonas AO, Taggart W, Brudi P. Lipid-altering efficacy of switching to ezetimibe/simvastatin 10/20 mg versus rosuvastatin 10 mg in high-risk patients with and without metabolic syndrome. Diab Vasc Dis Res. 2011 Oct;8(4):262-70. doi: 10.1177/1479164111418136. Epub 2011 Aug 22.

Viigimaa M, Vaverkova H, Farnier M, Averna M, Missault L, Hanson ME, Dong Q, Shah A, Brudi P. Ezetimibe/simvastatin 10/20 mg versus rosuvastatin 10 mg in high-risk hypercholesterolemic patients stratified by prior statin treatment potency. Lipids Health Dis. 2010 Nov 4;9:127. doi: 10.1186/1476-511X-9-127.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00479713 History of Changes
Other Study ID Numbers:	**0653A-809** 2007_552
Study First Received:	May 24, 2007
Results First Received:	February 11, 2009
Last Updated:	September 1, 2015
Health Authority:	France: Ministry of Health

Keywords provided by Merck Sharp & Dohme Corp.:
High Cholesterol

Additional relevant MeSH terms:

Hypercholesterolemia
Dyslipidemias
Hyperlipidemias
Lipid Metabolism Disorders
Metabolic Diseases
Anticholesteremic Agents
Ezetimibe
Rosuvastatin
Simvastatin
Antimetabolites
Enzyme Inhibitors
Hydroxymethylglutaryl-CoA Reductase Inhibitors
Hypolipidemic Agents
Lipid Regulating Agents
Molecular Mechanisms of Pharmacological Action
Pharmacologic Actions
Therapeutic Uses

ClinicalTrials.gov processed this record on March 30, 2016

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First received: May 24, 2007
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History of Changes

Results First Received: February 11, 2009

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Investigator); Primary Purpose: Treatment
Condition:	Hypercholesterolemia
Interventions:	Drug: ezetimibe (+) simvastatin Drug: Comparator : rosuvastatin calcium Drug: Comparator: Placebo (unspecified)

Participant Flow

Hide Participant Flow

Recruitment Details

Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations

Phase IV

First Participant In: 31-Mar-2007; Last Participant Last Visit 11-Mar-2008

85 centers worldwide (EX US)

Eligible participants include those on a stable dose of one of the following: rosuvastatin 5 mg; simvastatin 20 mg, 40 mg; atorvastatin 10, 20 mg; pravastatin 40 mg; fluvastatin 80 mg.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
Eligible participants were randomized at Visit 2 (Week 6) to either a combination tablet of ezetimibe/simvastatin (10 mg/20 mg) plus a matching placebo for rosuvastatin 10 mg (Group 1) or rosuvastatin 10 mg plus a matching placebo for the combination tablet (Group 2) for a 6-week treatment period.

Reporting Groups

	Description
Ezetemibe + Simvastatin	Ezetemibe 10 mg + Simvastatin 20 mg plus a matching placebo for rosuvastatin 10 mg QD (once a day) for 6 weeks
Rosuvastatin	Rosuvastatin 10 mg plus a matching placebo for the combination tablet QD (once a day) for 6 weeks

Participant Flow: Overall Study

	Ezetemibe + Simvastatin	Rosuvastatin
STARTED	**314**	**304**
COMPLETED	**301**	**295**
NOT COMPLETED	**13**	**9**
Adverse Event	**8**	**6**
Death	**1**	**0**
Lost to Follow-up	**0**	**1**
Protocol Violation	**0**	**1**
Withdrawal by Subject	**4**	**1**

Baseline Characteristics

Hide Baseline Characteristics

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
No text entered.

Reporting Groups

	Description
Ezetemibe + Simvastatin	Ezetemibe 10 mg + Simvastatin 20 mg plus a matching placebo for rosuvastatin 10 mg QD (once a day) for 6 weeks
Rosuvastatin	Rosuvastatin 10 mg plus a matching placebo for the combination tablet QD (once a day) for 6 weeks
Total	Total of all reporting groups

Baseline Measures

	Ezetemibe + Simvastatin	Rosuvastatin	Total
Number of Participants			

[units: participants]	314	304	618
Age [units: years] Mean (Full Range)	63.2 (38 to 82)	63.1 (27 to 80)	63.15 (27 to 82)
Gender [units: participants]			
Female	129	119	248
Male	185	185	370
Race/Ethnicity, Customized [units: participants]			
White	314	302	616
Black	0	2	2
Race/Ethnicity, Customized [units: Participants]			
Hispanic or Latino	37	43	80
Not Hispanic or Latino	277	261	538
Apolipoprotein B [units: mg/dL] Median (Standard Deviation)	1.20 (0.20)	1.18 (0.21)	1.19 (0.21)
C Reactive Protein [units: mg/dL] Median (Standard Deviation)	0.16 (0.26)	0.15 (0.26)	0.16 (0.26)
High Density Lipoprotein-Cholesterol [units: mg/dL] Mean (Standard Deviation)	1.43 (0.37)	1.43 (0.36)	1.43 (0.36)
Low Density Lipoprotein-Cholesterol (LDL-C) [units: mg/dL] Mean (Standard Deviation)	3.21 (0.42)	3.24 (0.44)	3.23 (0.43)
Low Density Lipoprotein-Cholesterol (LDL-C):High Density Lipoprotein-Cholesterol (HDL-C) ratio [units: LDL-C:HDL-C ratio] Mean (Standard Deviation)	2.38 (0.65)	2.40 (0.65)	2.39 (0.65)
Non-High Density Lipoprotein-Cholesterol (Non-HDL-C) [units: mg/dL] Mean (Standard Deviation)	3.95 (0.55)	3.95 (0.56)	3.95 (0.55)
Total Cholesterol [units: mg/dL] Mean (Standard Deviation)	5.38 (0.57)	5.38 (0.61)	5.38 (0.59)
Total cholesterol:High Density Lipoprotein-Cholesterol (HDL-C) ratio [units: Total cholesterol:HDL-C ratio] Mean (Standard Deviation)	3.94 (0.89)	3.96 (0.90)	3.95 (0.90)
Triglycerides [units: mg/dL] Median (Standard Deviation)	1.46 (0.86)	1.41 (0.87)	1.42 (0.88)

Outcome Measures

Hide All Outcome Measures

1. Primary: Percent Change in Low Density Lipoprotein-Cholesterol (LDL-C) at Study Endpoint After Six Weeks of Treatment [Time Frame: Baseline and 6 weeks]

Measure Type	Primary
Measure Title	Percent Change in Low Density Lipoprotein-Cholesterol (LDL-C) at Study Endpoint After Six Weeks of Treatment
Measure Description	Percent Change in LDL-C at study endpoint after six weeks of treatment is calculated as the difference between week 6 measure and baseline measure divided by baseline measure *100.
Time Frame	Baseline and 6 weeks
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full Analysis Set (FAS): The FAS population includes all randomized participants who took at least 1 dose of study medication and had a baseline (BL) value and at least one post BL value.

Reporting Groups

	Description
Ezetemibe + Simvastatin	Ezetemibe 10 mg + Simvastatin 20 mg plus a matching placebo for rosuvastatin 10 mg QD (once a day) for 6 weeks
Rosuvastatin	Rosuvastatin 10 mg plus a matching placebo for the combination tablet QD (once a day) for 6 weeks

Measured Values

	Ezetemibe + Simvastatin	**Rosuvastatin**
Number of Participants Analyzed [units: participants]	**305**	**297**
Percent Change in Low Density Lipoprotein-Cholesterol (LDL-C) at Study Endpoint After Six Weeks of Treatment [units: percent change from baseline] Least Squares Mean (95% Confidence Interval)	**-27.66 (-30.27 to -25.04)**	**-16.94 (-19.61 to -14.28)**

Statistical Analysis 1 for Percent Change in Low Density Lipoprotein-Cholesterol (LDL-C) at Study Endpoint After Six Weeks of Treatment

Groups [1]	All groups
Method [2]	ANOVA
P Value [3]	<=0.001
Mean Difference (Final Values) [4]	-10.72
Standard Error of the mean	(1.72)
95% Confidence Interval	-14.10 to -7.33

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.

[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Model terms: treatment, stratum, baseline (categorized based on quartiles) and center
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

2. Secondary: The Percentage of Participants Achieving Designated Low Density Lipoprotein-Cholesterol (LDL-C) Levels After 6 Weeks of Treatment [Time Frame: after 6 weeks of treatment]

Measure Type	Secondary
Measure Title	The Percentage of Participants Achieving Designated Low Density Lipoprotein-Cholesterol (LDL-C) Levels After 6 Weeks of Treatment
Measure Description	The percentage of participants who achieved a target LDL-C goal of < 100 mg/dL, of <70 mg/dL, and of <77 mg/dL at study endpoint after six weeks of treatment. The numerator is the number of participants in a treatment group who achieved a target LDL-C goal and the denominator is the total number of participants within that treatment group.
Time Frame	after 6 weeks of treatment
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full Analysis Set (FAS)

Reporting Groups

	Description
Ezetemibe + Simvastatin	Ezetemibe 10 mg + Simvastatin 20 mg plus a matching placebo for rosuvastatin 10 mg QD (once a day) for 6 weeks
Rosuvastatin	Rosuvastatin 10 mg plus a matching placebo for the combination tablet QD (once a day) for 6 weeks

Measured Values

	Ezetemibe + Simvastatin	**Rosuvastatin**
Number of Participants Analyzed [units: participants]	**305**	**297**
The Percentage of Participants Achieving Designated Low Density Lipoprotein-Cholesterol (LDL-C) Levels After 6 Weeks of Treatment [units: Percent of participant population]		
LDL-C <100	**72.46**	**56.23**
LDL-C <70	**25.25**	**11.11**

Statistical Analysis 1 for The Percentage of Participants Achieving Designated Low Density Lipoprotein-Cholesterol (LDL-C) Levels After 6 Weeks of Treatment

Groups [1]	All groups
Method [2]	Regression, Logistic
P Value [3]	<=0.001
Odds Ratio (OR) [4]	2.1
95% Confidence Interval	1.5 to 3.0

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	Percentage of Participants who Attained Target LDL-C Goal of < 100 mg/dL (2.59 mmol/L)
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Model terms: treatment, stratum and baseline LDL-C (continuous)
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 2 for The Percentage of Participants Achieving Designated Low Density Lipoprotein-Cholesterol (LDL-C) Levels After 6 Weeks of Treatment

Groups [1]	All groups
Method [2]	Regression, Logistic
P Value [3]	<=0.001
Odds Ratio (OR) [4]	2.8
95% Confidence Interval	1.8 to 4.4

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	Percentage of Participants who Attained Target LDL-C Goal of < 70 mg/dL (1.81 mmol/L)
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Model terms: treatment, stratum and baseline LDL-C (continuous)
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

3. Other Pre-specified: Percent Change From Baseline in Total Cholesterol [Time Frame: Baseline and 6 weeks]

Measure Type	Other Pre-specified

Measure Title	Percent Change From Baseline in Total Cholesterol
Measure Description	Percent change from baseline in total cholesterol at study endpoint after 6 weeks of treatment is calculated as the difference between week 6 measure and baseline measure divided by baseline measure *100.
Time Frame	Baseline and 6 weeks
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full Analysis Set (FAS): The FAS population includes all randomized participants who took at least 1 dose of study medication and had a baseline (BL) value and at least one post BL value.

Reporting Groups

	Description
Ezetemibe + Simvastatin	Ezetemibe 10 mg + Simvastatin 20 mg plus a matching placebo for rosuvastatin 10 mg QD (once a day) for 6 weeks
Rosuvastatin	Rosuvastatin 10 mg plus a matching placebo for the combination tablet QD (once a day) for 6 weeks

Measured Values

	Ezetemibe + Simvastatin	**Rosuvastatin**
Number of Participants Analyzed [units: participants]	**305**	**297**
Percent Change From Baseline in Total Cholesterol [units: percent change from baseline] Least Squares Mean (95% Confidence Interval)	**-17.53 (-19.36 to -15.71)**	**-10.33 (-12.19 to -8.47)**

Statistical Analysis 1 for Percent Change From Baseline in Total Cholesterol

Groups [1]	All groups
Method [2]	ANOVA
P Value [3]	<=0.001
Mean Difference (Final Values) [4]	-7.20
Standard Error of the mean	(1.20)
95% Confidence Interval	-9.56 to -4.84

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Model terms: treatment, stratum, baseline (categorized based on quartiles) and center
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.

[4]	Other relevant estimation information:
	No text entered.

4. Other Pre-specified: Percent Change From Baseline in Triglycerides. [Time Frame: Baseline and 6 weeks]

Measure Type	Other Pre-specified
Measure Title	Percent Change From Baseline in Triglycerides.
Measure Description	Percent change from baseline in triglycerides at study endpoint after 6 weeks of treatment is calculated as the difference between week 6 measure and baseline measure divided by baseline measure *100.
Time Frame	Baseline and 6 weeks
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full Analysis Set (FAS): The FAS population includes all randomized participants who took at least 1 dose of study medication and had a baseline (BL) value and at least one post BL value.

Reporting Groups

	Description
Ezetemibe + Simvastatin	Ezetemibe 10 mg + Simvastatin 20 mg plus a matching placebo for rosuvastatin 10 mg QD (once a day) for 6 weeks
Rosuvastatin	Rosuvastatin 10 mg plus a matching placebo for the combination tablet QD (once a day) for 6 weeks

Measured Values

	Ezetemibe + Simvastatin	**Rosuvastatin**
Number of Participants Analyzed [units: participants]	**305**	**297**
Percent Change From Baseline in Triglycerides. [units: percent change from baseline] Median (95% Confidence Interval)	**-11.00 (-15.25 to -6.80)**	**-5.26 (-9.92 to -1.17)**

Statistical Analysis 1 for Percent Change From Baseline in Triglycerides.

Groups [1]	All groups
Method [2]	Nonparametric ANOVA
P Value [3]	0.056
Median Difference (Final Values) [4]	-5.06
95% Confidence Interval	-9.56 to -0.30

[1]	Additional details about the analysis, such as null hypothesis and power calculation:

	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	ANOVA model based on Tukey's normalized ranks with term for treatment, stratum, baseline (categorized based on quartiles) and center.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	The median difference between treatments is based on the Hodges-Lehmann estimates of shift with a corresponding distribution-free Confidence Interval (CI) based on Wilcoxon's rank.

5. Other Pre-specified: Percent Change From Baseline in High Density Lipoprotein-Cholesterol (HDL-C) [Time Frame: Baseline and 6 weeks]

Measure Type	Other Pre-specified
Measure Title	Percent Change From Baseline in High Density Lipoprotein-Cholesterol (HDL-C)
Measure Description	Percent change from baseline in HDL-C at study endpoint after 6 weeks of treatment is calculated as the difference between week 6 measure and baseline measure divided by baseline measure *100.
Time Frame	Baseline and 6 weeks
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full Analysis Set (FAS): The FAS population includes all randomized participants who took at least 1 dose of study medication and had a baseline (BL) value and at least one post BL value.

Reporting Groups

	Description
Ezetemibe + Simvastatin	Ezetemibe 10 mg + Simvastatin 20 mg plus a matching placebo for rosuvastatin 10 mg QD (once a day) for 6 weeks
Rosuvastatin	Rosuvastatin 10 mg plus a matching placebo for the combination tablet QD (once a day) for 6 weeks

Measured Values

	Ezetemibe + Simvastatin	**Rosuvastatin**
Number of Participants Analyzed [units: participants]	**305**	**297**
Percent Change From Baseline in High Density Lipoprotein-Cholesterol (HDL-C) [units: percent change from baseline] Least Squares Mean (95% Confidence Interval)	**2.12 (0.34 to 3.89)**	**3.03 (1.22 to 4.85)**

Statistical Analysis 1 for Percent Change From Baseline in High Density Lipoprotein-Cholesterol (HDL-C)

[1]	

Groups	All groups
Method [2]	ANOVA
P Value [3]	0.433
Mean Difference (Final Values) [4]	-0.92
Standard Error of the mean	(1.17)
95% Confidence Interval	-3.21 to 1.38

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Model terms: treatment, stratum, baseline (categorized based on quartiles) and center.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

6. Other Pre-specified: Percent Change From Baseline in Non-High Density Lipoprotein-Cholesterol (Non-HDL-C) [Time Frame: Baseline and 6 weeks]

Measure Type	Other Pre-specified
Measure Title	Percent Change From Baseline in Non-High Density Lipoprotein-Cholesterol (Non-HDL-C)
Measure Description	Percent change from baseline in non HDL-C at study endpoint after 6 weeks of treatment is calculated as the difference between week 6 measure and baseline measure divided by baseline measure *100.
Time Frame	Baseline and 6 weeks
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full Analysis Set (FAS): The FAS population includes all randomized participants who took at least 1 dose of study medication and had a baseline (BL) value and at least one post BL value.

Reporting Groups

	Description
Ezetemibe + Simvastatin	Ezetemibe 10 mg + Simvastatin 20 mg plus a matching placebo for rosuvastatin 10 mg QD (once a day) for 6 weeks
Rosuvastatin	Rosuvastatin 10 mg plus a matching placebo for the combination tablet QD (once a day) for 6 weeks

Measured Values

	Ezetemibe + Simvastatin	**Rosuvastatin**

Number of Participants Analyzed [units: participants]	**305**	**297**
Percent Change From Baseline in Non-High Density Lipoprotein-Cholesterol (Non-HDL-C) [units: percent change from baseline] Least Squares Mean (95% Confidence Interval)	**-23.42 (-25.81 to 21.03)**	**-14.01 (-16.46 to -11.57)**

Statistical Analysis 1 for Percent Change From Baseline in Non-High Density Lipoprotein-Cholesterol (Non-HDL-C)

Groups [1]	All groups
Method [2]	ANOVA
P Value [3]	<=0.001
Mean Difference (Final Values) [4]	-9.41
Standard Error of the mean	(1.58)
95% Confidence Interval	-12.50 to -6.31

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Model terms: treatment, stratum, baseline (categorized based on quartiles) and center.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

7. Other Pre-specified: Percent Change From Baseline in Low Density Lipoprotein-Cholesterol (LDL-C)/High Density Lipoprotein-Cholesterol (HDL-C) Ratio [Time Frame: Baseline and 6 weeks]

Measure Type	Other Pre-specified
Measure Title	Percent Change From Baseline in Low Density Lipoprotein-Cholesterol (LDL-C)/High Density Lipoprotein-Cholesterol (HDL-C) Ratio
Measure Description	Percent change from baseline in LDL-C/HDL-C ratio at study endpoint after 6 weeks of treatment is calculated as the difference between week 6 measure and baseline measure divided by baseline measure *100.
Time Frame	Baseline and 6 weeks
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full Analysis Set (FAS): The FAS population includes all randomized participants who took at least 1 dose of study medication and had a baseline (BL) value and at least one post BL value.

Reporting Groups

	Description
Ezetemibe + Simvastatin	Ezetemibe 10 mg + Simvastatin 20 mg plus a matching placebo for rosuvastatin 10 mg QD (once a day) for 6 weeks
Rosuvastatin	Rosuvastatin 10 mg plus a matching placebo for the combination tablet QD (once a day) for 6 weeks

Measured Values

	Ezetemibe + Simvastatin	Rosuvastatin
Number of Participants Analyzed [units: participants]	**305**	**297**
Percent Change From Baseline in Low Density Lipoprotein-Cholesterol (LDL-C)/High Density Lipoprotein-Cholesterol (HDL-C) Ratio [units: percent change from baseline] Least Squares Mean (95% Confidence Interval)	**-27.41 (-30.42 to -24.40)**	**-17.82 (-20.89 to -14.75)**

Statistical Analysis 1 for Percent Change From Baseline in Low Density Lipoprotein-Cholesterol (LDL-C)/High Density Lipoprotein-Cholesterol (HDL-C) Ratio

Groups [1]	All groups
Method [2]	ANOVA
P Value [3]	<=0.001
Mean Difference (Final Values) [4]	-9.59
Standard Error of the mean	(1.98)
95% Confidence Interval	-13.49 to -5.69

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Model terms: treatment, stratum, baseline (categorized based on quartiles) and center.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

8. Other Pre-specified: Percent Change From Baseline in Total Cholesterol/High Density Lipoprotein-Cholesterol (HDL-C) Ratio [Time Frame: Baseline and 6 weeks]

Measure Type	Other Pre-specified
Measure Title	Percent Change From Baseline in Total Cholesterol/High Density Lipoprotein-Cholesterol (HDL-C) Ratio
Measure Description	Percent change from baseline in total cholesterol/HDL-C ratio at study endpoint after 6 weeks of treatment is calculated as the difference between week 6 measure and baseline measure divided by baseline measure *100.

Time Frame	Baseline and 6 weeks
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full Analysis Set (FAS): The FAS population includes all randomized participants who took at least 1 dose of study medication and had a baseline (BL) value and at least one post BL value.

Reporting Groups

	Description
Ezetemibe + Simvastatin	Ezetemibe 10 mg + Simvastatin 20 mg plus a matching placebo for rosuvastatin 10 mg QD (once a day) for 6 weeks
Rosuvastatin	Rosuvastatin 10 mg plus a matching placebo for the combination tablet QD (once a day) for 6 weeks

Measured Values

	Ezetemibe + Simvastatin	**Rosuvastatin**
Number of Participants Analyzed [units: participants]	**305**	**297**
Percent Change From Baseline in Total Cholesterol/High Density Lipoprotein-Cholesterol (HDL-C) Ratio [units: percent change from baseline] Least Squares Mean (95% Confidence Interval)	**-17.76 (-19.94 to -15.57)**	**-11.51 (-13.74 to -9.28)**

Statistical Analysis 1 for Percent Change From Baseline in Total Cholesterol/High Density Lipoprotein-Cholesterol (HDL-C) Ratio

Groups [1]	All groups
Method [2]	ANOVA
P Value [3]	<=0.001
Mean Difference (Final Values) [4]	-6.25
Standard Error of the mean	(1.44)
95% Confidence Interval	-9.07 to -3.43

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Model terms: treatment, stratum, baseline (categorized based on quartiles) and center.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

9. Other Pre-specified: Percent Change From Baseline in Apolipoprotein B [Time Frame: Baseline and 6 weeks]

Measure Type	Other Pre-specified
Measure Title	Percent Change From Baseline in Apolipoprotein B
Measure Description	Percent change from baseline in apolipoprotein (Apo) B at study endpoint after 6 weeks of treatment is calculated as the difference between week 6 measure and baseline measure divided by baseline measure *100.
Time Frame	Baseline and 6 weeks
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full Analysis Set (FAS): The FAS population includes all randomized participants who took at least 1 dose of study medication and had a baseline (BL) value and at least one post BL value.

Reporting Groups

	Description
Ezetemibe + Simvastatin	Ezetemibe 10 mg + Simvastatin 20 mg plus a matching placebo for rosuvastatin 10 mg QD (once a day) for 6 weeks
Rosuvastatin	Rosuvastatin 10 mg plus a matching placebo for the combination tablet QD (once a day) for 6 weeks

Measured Values

	Ezetemibe + Simvastatin	**Rosuvastatin**
Number of Participants Analyzed [units: participants]	**301**	**292**
Percent Change From Baseline in Apolipoprotein B [units: percent change from baseline] Least Squares Mean (95% Confidence Interval)	**-17.87 (-20.05 to -15.70)**	**-9.77 (-11.99 to -7.55)**

Statistical Analysis 1 for Percent Change From Baseline in Apolipoprotein B

Groups [1]	All groups
Method [2]	ANOVA
P Value [3]	<=0.001
Mean Difference (Final Values) [4]	-8.11
Standard Error of the mean	(1.43)
95% Confidence Interval	-10.91 to -5.30

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:

	Model terms: treatment, stratum, baseline (categorized based on quartiles) and center
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

10. Other Pre-specified: Percent Change From Baseline in High-sensitivity C (Hs-C) Reactive Protein [Time Frame: Baseline and 6 weeks]

Measure Type	Other Pre-specified
Measure Title	Percent Change From Baseline in High-sensitivity C (Hs-C) Reactive Protein
Measure Description	Percent change from baseline in hs-C reactive protein at study endpoint after 6 weeks of treatment is calculated as the difference between week 6 measure and baseline measure divided by baseline measure *100.
Time Frame	Baseline and 6 weeks
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full Analysis Set (FAS): The FAS population includes all randomized participants who took at least 1 dose of study medication and had a baseline (BL) value and at least one post BL value.

Reporting Groups

	Description
Ezetemibe + Simvastatin	Ezetemibe 10 mg + Simvastatin 20 mg plus a matching placebo for rosuvastatin 10 mg QD (once a day) for 6 weeks
Rosuvastatin	Rosuvastatin 10 mg plus a matching placebo for the combination tablet QD (once a day) for 6 weeks

Measured Values

	Ezetemibe + Simvastatin	**Rosuvastatin**
Number of Participants Analyzed [units: participants]	**301**	**293**
Percent Change From Baseline in High-sensitivity C (Hs-C) Reactive Protein [units: percent change from baseline] Median (95% Confidence Interval)	**-8.33 (-16.67 to 0.00)**	**0.00 (-7.14 to 6.25)**

Statistical Analysis 1 for Percent Change From Baseline in High-sensitivity C (Hs-C) Reactive Protein

Groups [1]	All groups
Method [2]	Nonparametric ANOVA
P Value [3]	0.172

Mean Difference (Final Values) [4]	-6.67
95% Confidence Interval	-16.67 to 2.87

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	ANOVA model based on Tukey's normalized ranks with term for treatment, stratum, baseline (categorized based on quartiles) and center
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	The median difference between treatments is based on the Hodges-Lehmann estimates of shift with a corresponding distribution-free CI based on Wilcoxon's rank

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	No text entered.
Additional Description	Adverse event tables include all participants who took at least one dose of study drug.

Reporting Groups

	Description
Ezetemibe + Simvastatin	Ezetemibe 10 mg + Simvastatin 20 mg plus a matching placebo for rosuvastatin 10 mg QD (once a day) for 6 weeks
Rosuvastatin	Rosuvastatin 10 mg plus a matching placebo for the combination tablet QD (once a day) for 6 weeks

Serious Adverse Events

	Ezetemibe + Simvastatin	**Rosuvastatin**
Total, serious adverse events		
# participants affected	**3**	**5**
General disorders		
Chest pain * 1		
# participants affected / at risk	**0/312 (0.00%)**	**2/304 (0.66%)**
Hepatobiliary disorders		
Cholangitis * 1		
# participants affected / at risk	**1/312 (0.32%)**	**0/304 (0.00%)**
Injury, poisoning and procedural complications		
* 1		

Accidental overdose		
# participants affected / at risk	**1/312 (0.32%)**	**0/304 (0.00%)**
In-stent arterial restenosis * 1		
# participants affected / at risk	**0/312 (0.00%)**	**1/304 (0.33%)**
Nervous system disorders		
Subarachnoid hemorrhage * 1		
# participants affected / at risk	**1/312 (0.32%)**	**0/304 (0.00%)**
Epileptic seizure * 1		
# participants affected / at risk	**0/312 (0.00%)**	**1/304 (0.33%)**
Skin and subcutaneous tissue disorders		
Skin eruption * 1		
# participants affected / at risk	**0/312 (0.00%)**	**1/304 (0.33%)**

* Events were collected by non-systematic assessment
1 Term from vocabulary, MedDRA

Other Adverse Events

Hide Other Adverse Events

Time Frame	No text entered.
Additional Description	Adverse event tables include all participants who took at least one dose of study drug.

Frequency Threshold

Threshold above which other adverse events are reported	0%

Reporting Groups

	Description
Ezetemibe + Simvastatin	Ezetemibe 10 mg + Simvastatin 20 mg plus a matching placebo for rosuvastatin 10 mg QD (once a day) for 6 weeks
Rosuvastatin	Rosuvastatin 10 mg plus a matching placebo for the combination tablet QD (once a day) for 6 weeks

Other Adverse Events

	Ezetemibe + Simvastatin	**Rosuvastatin**
Total, other (not including serious) adverse events		
# participants affected	**19**	**30**
Cardiac disorders		
Angina unstable * 1		
# participants affected / at risk	**1/312 (0.32%)**	**0/304 (0.00%)**
Bradycardia * 1		
# participants affected / at risk	**1/312 (0.32%)**	**0/304 (0.00%)**

Gastrointestinal disorders		
Abdominal pain [*1]		
# participants affected / at risk	**2/312 (0.64%)**	**2/304 (0.66%)**
Abdominal pain upper [*1]		
# participants affected / at risk	**1/312 (0.32%)**	**1/304 (0.33%)**
Diarrhoea [*1]		
# participants affected / at risk	**3/312 (0.96%)**	**1/304 (0.33%)**
Dry mouth [*1]		
# participants affected / at risk	**0/312 (0.00%)**	**1/304 (0.33%)**
Dyspepsia [*1]		
# participants affected / at risk	**3/312 (0.96%)**	**1/304 (0.33%)**
Nausea [*1]		
# participants affected / at risk	**2/312 (0.64%)**	**0/304 (0.00%)**
Salivary hypersecretion [*1]		
# participants affected / at risk	**1/312 (0.32%)**	**0/304 (0.00%)**
Vomitting [*1]		
# participants affected / at risk	**2/312 (0.64%)**	**0/304 (0.00%)**
General disorders		
Asthenia [*1]		
# participants affected / at risk	**0/312 (0.00%)**	**1/304 (0.33%)**
Chest pain [*1]		
# participants affected / at risk	**1/312 (0.32%)**	**0/304 (0.00%)**
Pain [*1]		
# participants affected / at risk	**0/312 (0.00%)**	**1/304 (0.33%)**
Immune system disorders		
Hypersensitivity [*1]		
# participants affected / at risk	**1/312 (0.32%)**	**0/304 (0.00%)**
Seasonal allergy [*1]		
# participants affected / at risk	**1/312 (0.32%)**	**0/304 (0.00%)**
Infections and infestations		
Ear infection [*1]		
# participants affected / at risk	**0/312 (0.00%)**	**1/304 (0.33%)**
Gastroenteritis [*1]		
# participants affected / at risk	**0/312 (0.00%)**	**1/304 (0.33%)**
Gastroenteritis viral [*1]		
# participants affected / at risk	**0/312 (0.00%)**	**1/304 (0.33%)**
Localised infection [*1]		
# participants affected / at risk	**0/312 (0.00%)**	**1/304 (0.33%)**
Nasopharyngitis [*1]		
# participants affected / at risk	**1/312 (0.32%)**	**0/304 (0.00%)**
Paronychia [*1]		

# participants affected / at risk	0/312 (0.00%)	1/304 (0.33%)
Pharyngitis * 1		
# participants affected / at risk	1/312 (0.32%)	0/304 (0.00%)
Sinusitis * 1		
# participants affected / at risk	1/312 (0.32%)	0/304 (0.00%)
Tooth abscess * 1		
# participants affected / at risk	0/312 (0.00%)	1/304 (0.33%)
Bronchitis * 1		
# participants affected / at risk	2/312 (0.64%)	0/304 (0.00%)
Injury, poisoning and procedural complications		
Contusion * 1		
# participants affected / at risk	0/312 (0.00%)	1/304 (0.33%)
Deafness traumatic * 1		
# participants affected / at risk	1/312 (0.32%)	0/304 (0.00%)
Fall * 1		
# participants affected / at risk	1/312 (0.32%)	0/304 (0.00%)
Rib fracture * 1		
# participants affected / at risk	1/312 (0.32%)	0/304 (0.00%)
Upper limb fracture * 1		
# participants affected / at risk	0/312 (0.00%)	1/304 (0.33%)
Investigations		
Blood pressure increased * 1		
# participants affected / at risk	0/312 (0.00%)	1/304 (0.33%)
Metabolism and nutrition disorders		
Anorexia * 1		
# participants affected / at risk	1/312 (0.32%)	0/304 (0.00%)
Musculoskeletal and connective tissue disorders		
Arthralgia * 1		
# participants affected / at risk	0/312 (0.00%)	1/304 (0.33%)
Bursitis * 1		
# participants affected / at risk	0/312 (0.00%)	1/304 (0.33%)
Flank pain * 1		
# participants affected / at risk	1/312 (0.32%)	0/304 (0.00%)
Myalgia * 1		
# participants affected / at risk	3/312 (0.96%)	2/304 (0.66%)
Osteoarthritis * 1		
# participants affected / at risk	1/312 (0.32%)	0/304 (0.00%)
Sensation of heaviness * 1		
# participants affected / at risk	0/312 (0.00%)	1/304 (0.33%)
Spinal osteoarthritis * 1		
# participants affected / at risk	0/312 (0.00%)	1/304 (0.33%)

Nervous system disorders		
Carpal tunnel syndrome [*1]		
# participants affected / at risk	**0/312 (0.00%)**	**1/304 (0.33%)**
Headache [*1]		
# participants affected / at risk	**1/312 (0.32%)**	**0/304 (0.00%)**
Memory impairment [*1]		
# participants affected / at risk	**0/312 (0.00%)**	**1/304 (0.33%)**
Paraesthesia [*1]		
# participants affected / at risk	**0/312 (0.00%)**	**1/304 (0.33%)**
Syncope vasovagal [*1]		
# participants affected / at risk	**0/312 (0.00%)**	**1/304 (0.33%)**
Psychiatric disorders		
Insomnia [*1]		
# participants affected / at risk	**0/312 (0.00%)**	**1/304 (0.33%)**
Nervousness [*1]		
# participants affected / at risk	**0/312 (0.00%)**	**1/304 (0.33%)**
Renal and urinary disorders		
Nephrolithiasis [*1]		
# participants affected / at risk	**0/312 (0.00%)**	**1/304 (0.33%)**
Respiratory, thoracic and mediastinal disorders		
Throat tightness [*1]		
# participants affected / at risk	**0/312 (0.00%)**	**1/304 (0.33%)**
Skin and subcutaneous tissue disorders		
Rash [*1]		
# participants affected / at risk	**0/312 (0.00%)**	**1/304 (0.33%)**
Vascular disorders		
Hypertension [*1]		
# participants affected / at risk	**0/312 (0.00%)**	**1/304 (0.33%)**

* Events were collected by non-systematic assessment
1 Term from vocabulary, MedDRA

Limitations and Caveats

Hide Limitations and Caveats

Limitations of the study, such as early termination leading to small numbers of participants analyzed and technical problems with measurement leading to unreliable or uninterpretable data
No text entered.

More Information

Hide More Information

Certain Agreements:

Principal Investigators are **NOT** employed by the organization sponsoring the study.
There **IS** an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.
The agreement is: ☐ 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**. The sponsor cannot require changes to the communication and cannot extend the embargo. ☐ 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 **more than 60 days but less than or equal to 180 days**. The sponsor cannot require changes to the communication and cannot extend the embargo. ☑ Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed. **Restriction Description:** Merck agreements may vary with individual investigators, but will not prohibit any investigator from publishing. Merck supports the publication of results from all centers of a multi-center trial but requests that reports based on single-site data not precede the primary publication of the entire clinical trial.

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Publications:

Farnier M, Averna M, Missault L, Vaverkova H, Viigimaa M, Massaad R, Vandormael K, Johnson-Levonas AO, Brudi P. Lipid-altering efficacy of ezetimibe/simvastatin 10/20 mg compared with rosuvastatin 10 mg in high-risk hypercholesterolaemic patients inadequately controlled with prior statin monotherapy - The IN-CROSS study. Int J Clin Pract. 2009 Apr;63(4):547-59. doi: 10.1111/j.1742-1241.2009.02022.x. Epub 2009 Feb 16.

Publications automatically indexed to this study:

Averna M, Missault L, Vaverkova H, Farnier M, Viigimaa M, Dong Q, Shah A, Johnson-Levonas AO, Taggart W, Brudi P. Lipid-altering efficacy of switching to ezetimibe/simvastatin 10/20 mg versus rosuvastatin 10 mg in high-risk patients with and without metabolic syndrome. Diab Vasc Dis Res. 2011 Oct;8(4):262-70. doi: 10.1177/1479164111418136. Epub 2011 Aug 22.

Viigimaa M, Vaverkova H, Farnier M, Averna M, Missault L, Hanson ME, Dong Q, Shah A, Brudi P. Ezetimibe/simvastatin 10/20 mg versus rosuvastatin 10 mg in high-risk hypercholesterolemic patients stratified by prior statin treatment potency. Lipids Health Dis. 2010 Nov 4;9:127. doi: 10.1186/1476-511X-9-127.

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