A Study to Assess the Cholesterol Lowering Effect of Ezetimibe/Simvastatin Combination Tablet Compared to Another Cholesterol Lowering Drug in Elderly Patients With High Cholesterol at High or Moderately High Risk for Coronary Heart Disease (0653A-128)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

Collaborator:
Merck Shering-Plough JV Study

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

ClinicalTrials.gov Identifier:
NCT00535405

First received: September 25, 2007
Last updated: January 19, 2015
Last verified: January 2015
History of Changes

Purpose

A multicenter study to evaluate the safety and efficacy of ezetimibe/simvastatin versus atorvastatin in elderly patients with high cholesterol at high or moderately high risk for coronary heart disease.

Condition	Intervention	Phase
Hypercholesterolemia	Drug: Atorvastatin 10 mg Drug: Ezetimibe 10 mg/simvastatin 20 mg Drug: Atorvastatin 20 mg Drug: Ezetimibe 10 mg/simvastatin 40 mg Drug: Atorvastatin 40 mg	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 Multicenter, Randomized, Double-Blind, Parallel, 12-Week Study to Evaluate the Efficacy and Safety of Ezetimibe/Simvastatin Combination Tablet Versus Atorvastatin in Elderly Patients With Hypercholesterolemia at High or Moderately High Risk for Coronary Heart Disease

Resource links provided by NLM:

MedlinePlus related topics: Cholesterol Coronary Artery Disease Heart Diseases

Drug Information available for: Simvastatin Atorvastatin Atorvastatin calcium Ezetimibe

Genetic and Rare Diseases Information Center resources: Sphingolipidosis

U.S. FDA Resources

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

Primary Outcome Measures:

- Percent Change From Baseline in Low Density Lipoprotein (LDL-C) at Week 12 [Time Frame: Baseline and 12 weeks] [Designated as safety issue: No]

Secondary Outcome Measures:

- Percentage of Patients Who Achieved LDL-C <70 mg/dL at Week 12 [Time Frame: 12 weeks] [Designated as safety issue: No]
- Percentage of Patients Without Atherosclerosis Vascular Disease (AVD) Who Achieved LDL-C <100 mg/dL or Patients With AVD Who Achieved LDL-C <70 mg/dL at Week 12 [Time Frame: 12 Weeks] [Designated as safety issue: No]

  Patients with AVD Who Achieved LDL-C <70 mg/dL. AVD was defined as a history of myocardial infarction, stable angina, coronary artery procedures or evidence of clinically significant myocardial ischemia.

- Percentage of Patients Who Achieved LDL-C <100 mg/dL at Week 12 [Time Frame: 12 Weeks] [Designated as safety issue: No]
- Percentage of Patients With High Risk for CHD Who Achieved LDL-C <70 mg/dL at Week 12 [Time Frame: 12 Weeks] [Designated as safety issue: No]

  Risk was assessed utilizing a history of established CHD or CHD risk equivalent and Framingham Risk scoring.

- Percentage of Patients With AVD Who Achieved LDL-C <70 mg/dL at Week 12 [Time Frame: 12 Weeks] [Designated as safety issue: No]

  Patients with AVD Who Achieved LDL-C <70 mg/dL. AVD was defined as a history of myocardial infarction, stable angina, coronary artery procedures or evidence of clinically significant myocardial ischemia.

Enrollment:	1289
Study Start Date:	November 2007
Study Completion Date:	March 2009
Primary Completion Date:	March 2009 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: 1 Each patient will receive 1 active treatment dose & 2 Placebo (Pbo) doses or 2 active treatment doses & 1 Pbo dose at randomization according to a predetermined partial blinding schedule to reduce the number of pills from 5 to 3 per patient per day for 12 weeks.	Drug: Atorvastatin 10 mg Atorvastatin 10 mg and Placebo for ezetimibe and placebo for simvastatin once daily for 12 weeks
Experimental: 2 Each patient will receive 1 active treatment dose & 2 Pbo doses or 2 active treatment doses & 1 Pbo dose at randomization according to a predetermined partial blinding schedule to reduce the number of pills from 5 to 3 per patient per day for 12 weeks.	Drug: Ezetimibe 10 mg/simvastatin 20 mg Ezetimibe 10 mg/simvastatin 20 mg and Placebo for atorvastatin once daily for 12 weeks
Experimental: 3 Each patient will receive 1 active treatment dose & 2 Pbo doses or 2 active treatment doses & 1 Pbo dose at randomization according to a predetermined partial blinding schedule to reduce the number of pills from 5 to 3 per patient per day for 12 weeks.	Drug: Atorvastatin 20 mg Atorvastatin 20 mg and Placebo for ezetimibe and placebo for simvastatin once daily for 12 weeks
Experimental: 4 Each patient will receive 1 active treatment dose & 2 Pbo doses or 2 active treatment doses & 1 Pbo dose at randomization according to a predetermined partial blinding schedule to reduce the number of pills from 5 to 3 per patient per day for 12 weeks.	Drug: Ezetimibe 10 mg/simvastatin 40 mg Ezetimibe 10 mg/simvastatin 40 mg and Placebo for atorvastatin once daily for 12 weeks
Experimental: 5 Each patient will receive 1 active treatment dose & 2 Pbo doses or 2 active treatment doses & 1 Pbo dose at randomization according to a predetermined partial blinding schedule to reduce the number of	Drug: Atorvastatin 40 mg Atorvastatin 40 mg and Placebo for ezetimibe and placebo for

pills from 5 to 3 per patient per day for 12 weeks.	simvastatin once daily for 12 weeks

Eligibility

Ages Eligible for Study: 65 Years and older
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- Patient has a cholesterol level of 130 mg/dL or greater
- Patient is willing to maintain a cholesterol lowering diet for as long as they are in the study
- Patient is at moderate high risk or high risk for coronary heart disease per the National Cholesterol Education Program Adult Treatment Panel III (NCEP ATPIII) guidelines

Exclusion Criteria:

- Patient weighs less than 100 lbs
- Patient has an allergy to ezetimibe, simvastatin or atorvastatin

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: NCT00535405

Sponsors and Collaborators

Merck Sharp & Dohme Corp.

Merck Shering-Plough JV Study

Investigators

Study Director: Medical Monitor Merck Sharp & Dohme Corp.

More Information

Publications:

Foody JM, Brown WV, Zieve F, Adewale AJ, Flaim D, Lowe RS, Jones-Burton C, Tershakovec AM. Safety and efficacy of ezetimibe/simvastatin combination versus atorvastatin alone in adults ≥65 years of age with hypercholesterolemia and with or at moderately high/high risk for coronary heart disease (the VYTELD study). Am J Cardiol. 2010 Nov 1;106(9):1255-63. doi: 10.1016/j.amjcard.2010.06.051.

Responsible Party: Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier: NCT00535405 History of Changes
Other Study ID Numbers: 0653A-128, 2007_588
Study First Received: September 25, 2007
Results First Received: April 26, 2010
Last Updated: January 19, 2015
Health Authority: United States: Food and Drug Administration

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

Additional relevant MeSH terms:

Coronary Artery Disease	Anticholesteremic Agents
Coronary Disease	Atorvastatin

Heart Diseases
Hypercholesterolemia
Myocardial Ischemia
Arterial Occlusive Diseases
Arteriosclerosis
Cardiovascular Diseases
Dyslipidemias
Hyperlipidemias
Lipid Metabolism Disorders
Metabolic Diseases
Vascular Diseases

Ezetimibe
Simvastatin
Antimetabolites
Enzyme Inhibitors
Hydroxymethylglutaryl-CoA Reductase Inhibitors
Hypolipidemic Agents
Lipid Regulating Agents
Molecular Mechanisms of Pharmacological Action
Pharmacologic Actions
Therapeutic Uses

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Last verified: January 2015
History of Changes

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

Results First Received: April 26, 2010

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: Atorvastatin 10 mg Drug: Ezetimibe 10 mg/simvastatin 20 mg Drug: Atorvastatin 20 mg Drug: Ezetimibe 10 mg/simvastatin 40 mg Drug: Atorvastatin 40 mg

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 III

First Patient In 08-Nov-2007; Last Patient Last Visit 23-Mar-2009

Eligible patients include drug-naïve patients or patients rendered naïve with the appropriate prior washout at moderately high or high risk for coronary heart disease 65 years and older.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
The study evaluated patients ≥ 65 years of age at moderately high or high risk for Coronary Heart Disease (CHD), with or without atherosclerotic vascular disease. The study was a 3-week single-blind placebo run-in period and a 12-week active treatment period where patients were equally randomized to one of 5 treatment groups for 12 weeks

Reporting Groups

	Description
Atorvastatin 10 mg	Atorvastatin (Atorva) 10 mg once daily for 12 weeks
Ezetimibe 10 mg/Simvastatin 20 mg	Ezetimibe (EZ) 10 mg/simvastatin (Simva) 20 mg once daily for 12 weeks
Atorvastatin 20 mg	Atorvastatin 20 mg once daily for 12 weeks
Ezetimibe 10 mg/Simvastatin 40 mg	Ezetimibe 10 mg/simvastatin 40 mg once daily for 12 weeks
Atorva 40 mg	Atorvastatin 40 mg once daily for 12 weeks

Participant Flow: Overall Study

	Atorvastatin 10 mg	**Ezetimibe 10 mg/Simvastatin 20 mg**	**Atorvastatin 20 mg**	**Ezetimibe 10 mg/Simvastatin 40 mg**	**Atorva 40 mg**
STARTED	**257**	**259**	**259**	**257**	**257**
COMPLETED	**240**	**233**	**241**	**235**	**241**
NOT COMPLETED	**17**	**26**	**18**	**22**	**16**
Adverse Event	**6**	**8**	**3**	**8**	**6**
Lost to Follow-up	**1**	**3**	**3**	**2**	**1**
Physician Decision	**3**	**2**	**0**	**1**	**1**
Protocol Violation	**2**	**2**	**2**	**1**	**0**
Withdrawal by Subject	**5**	**11**	**10**	**10**	**8**

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
Atorvastatin 10 mg	Atorvastatin (Atorva) 10 mg once daily for 12 weeks
Ezetimibe 10 mg/Simvastatin 20 mg	Ezetimibe (EZ) 10 mg/simvastatin (Simva) 20 mg once daily for 12 weeks
Atorvastatin 20 mg	Atorvastatin 20 mg once daily for 12 weeks

Ezetimibe 10 mg/Simvastatin 40 mg	Ezetimibe 10 mg/simvastatin 40 mg once daily for 12 weeks
Atorva 40 mg	Atorvastatin 40 mg once daily for 12 weeks
Total	Total of all reporting groups

Baseline Measures

	Atorvastatin 10 mg	Ezetimibe 10 mg/Simvastatin 20 mg	Atorvastatin 20 mg	Ezetimibe 10 mg/Simvastatin 40 mg	Atorva 40 mg	Total
Number of Participants [units: participants]	257	259	259	257	257	1289
Age [units: years] Mean (Full Range)	72.1 (65 to 94)	71.8 (65 to 95)	71.7 (65 to 90)	72.2 (65 to 96)	72.1 (65 to 88)	72.0 (65 to 96)
Gender [units: participants]						
Female	172	146	175	153	163	809
Male	85	113	84	104	94	480
Race/Ethnicity, Customized [units: participants]						
Asian	10	6	12	8	10	46
Black	2	2	8	6	9	27
Other	21	27	30	29	28	135
White	224	224	209	214	210	1081

Outcome Measures

Hide All Outcome Measures

1. Primary: Percent Change From Baseline in Low Density Lipoprotein (LDL-C) at Week 12 [Time Frame: Baseline and 12 weeks]

Measure Type	Primary
Measure Title	Percent Change From Baseline in Low Density Lipoprotein (LDL-C) at Week 12
Measure Description	No text entered.
Time Frame	Baseline and 12 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 patients with baseline (BL) value and at least one valid after-BL value. After-BL measurements up to 3 days following the last dose of double-blind study medication were included in the analysis.

Reporting Groups

	Description

Atorvastatin 10 mg	Atorvastatin (Atorva) 10 mg once daily for 12 weeks
Ezetimibe 10 mg/Simvastatin 20 mg	Ezetimibe (EZ) 10 mg/simvastatin (Simva) 20 mg once daily for 12 weeks
Atorvastatin 20 mg	Atorvastatin 20 mg once daily for 12 weeks
Ezetimibe 10 mg/Simvastatin 40 mg	Ezetimibe 10 mg/simvastatin 40 mg once daily for 12 weeks
Atorva 40 mg	Atorvastatin 40 mg once daily for 12 weeks

Measured Values

	Atorvastatin 10 mg	Ezetimibe 10 mg/Simvastatin 20 mg	Atorvastatin 20 mg	Ezetimibe 10 mg/Simvastatin 40 mg	Atorva 40 mg
Number of Participants Analyzed [units: participants]	**242**	**232**	**238**	**236**	**239**
Percent Change From Baseline in Low Density Lipoprotein (LDL-C) at Week 12 [units: Percent change in LDL-C] Least Squares Mean (95% Confidence Interval)	**-39.5 (-41.4 to -37.5)**	**-54.2 (-56.1 to -52.2)**	**-46.6 (-48.6 to -44.7)**	**-59.1 (-61.0 to -57.1)**	**-50.8 (-52.8 to -48.9)**

Statistical Analysis 1 for Percent Change From Baseline in Low Density Lipoprotein (LDL-C) at Week 12

Groups [1]	Atorvastatin 10 mg vs. Ezetimibe 10 mg/Simvastatin 20 mg
Method [2]	ANCOVA
P Value [3]	<0.001
Mean Difference (Final Values) [4]	-14.7
Standard Error of the mean	(1.4)
95% Confidence Interval	-17.5 to -12.0

[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:
	ANCOVA mixed model with fixed effects for treatment, baseline LDL-C, study week, treatment by study week interaction, and a random subject effect.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	Reported p-value is multiplicity-adjusted. Hochberg procedure was used to adjust for multiple comparisons.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 2 for Percent Change From Baseline in Low Density Lipoprotein (LDL-C) at Week 12

Groups [1]	Ezetimibe 10 mg/Simvastatin 20 mg vs. Atorvastatin 20 mg
Method [2]	ANCOVA
P Value [3]	<0.001

Mean Difference (Final Values) [4]	-7.5
Standard Error of the mean	(1.4)
95% Confidence Interval	-10.3 to -4.8

[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:
	ANCOVA mixed model with fixed effects for treatment, baseline LDL-C, study week, treatment by study week interaction, and a random subject effect.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	Reported p-value is multiplicity-adjusted. Hochberg procedure was used to adjust for multiple comparisons.
[4]	Other relevant estimation information:
	No text entered.

Statistical Analysis 3 for Percent Change From Baseline in Low Density Lipoprotein (LDL-C) at Week 12

Groups [1]	Ezetimibe 10 mg/Simvastatin 40 mg vs. Atorva 40 mg
Method [2]	ANCOVA
P Value [3]	<0.001
Mean Difference (Final Values) [4]	-8.2
Standard Error of the mean	(1.4)
95% Confidence Interval	-11.0 to -5.5

[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:
	ANCOVA mixed model with fixed effects for treatment, baseline LDL-C, study week, treatment by study week interaction, and a random subject effect.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	Reported p-value is multiplicity-adjusted. Hochberg procedure was used to adjust for multiple comparisons.
[4]	Other relevant estimation information:
	No text entered.

2. Secondary: Percentage of Patients Who Achieved LDL-C <70 mg/dL at Week 12 [Time Frame: 12 weeks]

Measure Type	Secondary
Measure Title	Percentage of Patients Who Achieved LDL-C <70 mg/dL at Week 12
Measure Description	No text entered.
Time Frame	12 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 patients with baseline (BL) value and at least one valid after-BL value. After-BL measurements up to 3 days following the last dose of double-blind study medication were included in the analysis.

Reporting Groups

	Description
Atorvastatin 10 mg	Atorvastatin (Atorva) 10 mg once daily for 12 weeks
Ezetimibe 10 mg/Simvastatin 20 mg	Ezetimibe (EZ) 10 mg/simvastatin (Simva) 20 mg once daily for 12 weeks
Atorvastatin 20 mg	Atorvastatin 20 mg once daily for 12 weeks
Ezetimibe 10 mg/Simvastatin 40 mg	Ezetimibe 10 mg/simvastatin 40 mg once daily for 12 weeks
Atorva 40 mg	Atorvastatin 40 mg once daily for 12 weeks

Measured Values

	Atorvastatin 10 mg	**Ezetimibe 10 mg/Simvastatin 20 mg**	**Atorvastatin 20 mg**	**Ezetimibe 10 mg/Simvastatin 40 mg**	**Atorva 40 mg**
Number of Participants Analyzed [units: participants]	**242**	**232**	**238**	**236**	**239**
Percentage of Patients Who Achieved LDL-C <70 mg/dL at Week 12 [units: Percent of Patients] Mean (Standard Error)	**9.9 (1.92)**	**51.3 (3.28)**	**26.1 (2.85)**	**68.2 (3.03)**	**38.1 (3.14)**

Statistical Analysis 1 for Percentage of Patients Who Achieved LDL-C <70 mg/dL at Week 12

Groups [1]	Atorvastatin 10 mg vs. Ezetimibe 10 mg/Simvastatin 20 mg
Method [2]	Logistic Regression using GEE
P Value [3]	<0.001
Ratio of odds [4]	12.62
Standard Error of the mean	(3.23)
95% Confidence Interval	7.64 to 20.83

[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 include terms for treatment, baseline LDL-C, study week and treatment by study week interaction. Generalized Estimating Equations (GEE)
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:

	Reported p-value is multiplicity-adjusted. Hochberg procedure was used to adjust for multiple comparisons.
[4]	Other relevant estimation information:
	Ratio of odds of achieving pre-specified LDL-C level on EZ/Simva versus Atorva

Statistical Analysis 2 for Percentage of Patients Who Achieved LDL-C <70 mg/dL at Week 12

Groups [1]	Ezetimibe 10 mg/Simvastatin 20 mg vs. Atorvastatin 20 mg
Method [2]	Logistic Regression using GEE
P Value [3]	<0.001
Ratio of odds [4]	3.83
Standard Error of the mean	(0.83)
95% Confidence Interval	2.51 to 5.85

[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 include terms for treatment, baseline LDL-C, study week and treatment by study week interaction.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	Reported p-value is multiplicity-adjusted. Hochberg procedure was used to adjust for multiple comparisons.
[4]	Other relevant estimation information:
	Ratio of odds of achieving pre-specified LDL-C level on EZ/Simva versus Atorva

Statistical Analysis 3 for Percentage of Patients Who Achieved LDL-C <70 mg/dL at Week 12

Groups [1]	Ezetimibe 10 mg/Simvastatin 40 mg vs. Atorva 40 mg
Method [2]	Logistic Regression using GEE
P Value [3]	<0.001
Ratio of odds [4]	3.66
Standard Error of the mean	(0.79)
95% Confidence Interval	2.39 to 5.60

[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 include terms for treatment, baseline LDL-C, study week and treatment by study week interaction.
[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:
	Ratio of odds of achieving pre-specified LDL-C level on EZ/Simva versus Atorva

3. Secondary: Percentage of Patients Without Atherosclerosis Vascular Disease (AVD) Who Achieved LDL-C <100 mg/dL or Patients With AVD Who Achieved LDL-C <70 mg/dL at Week 12 [Time Frame: 12 Weeks]

Measure Type	Secondary
Measure Title	Percentage of Patients Without Atherosclerosis Vascular Disease (AVD) Who Achieved LDL-C <100 mg/dL or Patients With AVD Who Achieved LDL-C <70 mg/dL at Week 12
Measure Description	Patients with AVD Who Achieved LDL-C <70 mg/dL. AVD was defined as a history of myocardial infarction, stable angina, coronary artery procedures or evidence of clinically significant myocardial ischemia.
Time Frame	12 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 patients with baseline (BL) value and at least one valid after-BL value. After-BL measurements up to 3 days following the last dose of double-blind study medication were included in the analysis.

Reporting Groups

	Description
Atorvastatin 10 mg	Atorvastatin (Atorva) 10 mg once daily for 12 weeks
Ezetimibe 10 mg/Simvastatin 20 mg	Ezetimibe (EZ) 10 mg/simvastatin (Simva) 20 mg once daily for 12 weeks
Atorvastatin 20 mg	Atorvastatin 20 mg once daily for 12 weeks
Ezetimibe 10 mg/Simvastatin 40 mg	Ezetimibe 10 mg/simvastatin 40 mg once daily for 12 weeks
Atorva 40 mg	Atorvastatin 40 mg once daily for 12 weeks

Measured Values

	Atorvastatin 10 mg	**Ezetimibe 10 mg/Simvastatin 20 mg**	**Atorvastatin 20 mg**	**Ezetimibe 10 mg/Simvastatin 40 mg**	**Atorva 40 mg**
Number of Participants Analyzed [units: participants]	**242**	**232**	**238**	**236**	**239**
Percentage of Patients Without Atherosclerosis Vascular Disease (AVD) Who Achieved LDL-C <100 mg/dL or Patients With AVD Who Achieved LDL-C <70 mg/dL at Week 12 [units: Percent of Patients] Mean (Standard Error)	**45.0 (3.20)**	**69.0 (3.04)**	**61.3 (3.16)**	**82.1 (2.50)**	**69.9 (2.97)**

Statistical Analysis 1 for Percentage of Patients Without Atherosclerosis Vascular Disease (AVD) Who Achieved LDL-C <100 mg/dL or Patients With AVD Who Achieved LDL-C <70 mg/dL at Week 12

Groups [1]	Atorvastatin 10 mg vs. Ezetimibe 10 mg/Simvastatin 20 mg
Method [2]	Logistic Regression using GEE
P Value [3]	<0.001

Ratio of odds [4]	3.05
Standard Error of the mean	(0.62)
95% Confidence Interval	2.04 to 4.55

[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 include terms for treatment, baseline LDL-C, study week and treatment by study week interaction.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	Reported p-value is multiplicity-adjusted. Hochberg procedure was used to adjust for multiple comparisons.
[4]	Other relevant estimation information:
	Ratio of odds of achieving pre-specified LDL-C level on EZ/Simva versus Atorva

Statistical Analysis 2 for Percentage of Patients Without Atherosclerosis Vascular Disease (AVD) Who Achieved LDL-C <100 mg/dL or Patients With AVD Who Achieved LDL-C <70 mg/dL at Week 12

Groups [1]	Ezetimibe 10 mg/Simvastatin 20 mg vs. Atorvastatin 20 mg
Method [2]	Logistic Regression using GEE
P Value [3]	0.039
Ratio of odds [4]	1.54
Standard Error of the mean	(0.32)
95% Confidence Interval	1.02 to 2.32

[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 include terms for treatment, baseline LDL-C, study week and treatment by study week interaction.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	Reported p-value is multiplicity-adjusted. Hochberg procedure was used to adjust for multiple comparisons.
[4]	Other relevant estimation information:
	Ratio of odds of achieving pre-specified LDL-C level on EZ/Simva versus Atorva

Statistical Analysis 3 for Percentage of Patients Without Atherosclerosis Vascular Disease (AVD) Who Achieved LDL-C <100 mg/dL or Patients With AVD Who Achieved LDL-C <70 mg/dL at Week 12

Groups [1]	Ezetimibe 10 mg/Simvastatin 40 mg vs. Atorva 40 mg
Method [2]	Logistic Regression using GEE
P Value [3]	0.023
Ratio of odds [4]	1.81
Standard Error of the mean	(0.43)

95% Confidence Interval	1.14 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:
	Model include terms for treatment, baseline LDL-C, study week and treatment by study week interaction.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	Reported p-value is multiplicity-adjusted. Hochberg procedure was used to adjust for multiple comparisons.
[4]	Other relevant estimation information:
	Ratio of odds of achieving pre-specified LDL-C level on EZ/Simva versus Atorva

4. Secondary: Percentage of Patients Who Achieved LDL-C <100 mg/dL at Week 12 [Time Frame: 12 Weeks]

Measure Type	Secondary
Measure Title	Percentage of Patients Who Achieved LDL-C <100 mg/dL at Week 12
Measure Description	No text entered.
Time Frame	12 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 patients with baseline (BL) value and at least one valid after-BL value. After-BL measurements up to 3 days following the last dose of double-blind study medication were included in the analysis.

Reporting Groups

	Description
Atorvastatin 10 mg	Atorvastatin (Atorva) 10 mg once daily for 12 weeks
Ezetimibe 10 mg/Simvastatin 20 mg	Ezetimibe (EZ) 10 mg/simvastatin (Simva) 20 mg once daily for 12 weeks
Atorvastatin 20 mg	Atorvastatin 20 mg once daily for 12 weeks
Ezetimibe 10 mg/Simvastatin 40 mg	Ezetimibe 10 mg/simvastatin 40 mg once daily for 12 weeks
Atorva 40 mg	Atorvastatin 40 mg once daily for 12 weeks

Measured Values

	Atorvastatin 10 mg	**Ezetimibe 10 mg/Simvastatin 20 mg**	**Atorvastatin 20 mg**	**Ezetimibe 10 mg/Simvastatin 40 mg**	**Atorva 40 mg**
Number of Participants Analyzed [units: participants]	**242**	**232**	**238**	**236**	**239**
Percentage of Patients Who Achieved LDL-C <100 mg/dL at Week 12	**58.7 (3.17)**	**83.6 (2.43)**	**76.9 (2.73)**	**90.3 (1.93)**	**79.5**

[units: Percent of Patients] Mean (Standard Error)					**(2.61)**

Statistical Analysis 1 for Percentage of Patients Who Achieved LDL-C <100 mg/dL at Week 12

Groups [1]	Atorvastatin 10 mg vs. Ezetimibe 10 mg/Simvastatin 20 mg
Method [2]	Logistic Regression using GEE
P Value [3]	<0.001
Ratio of odds [4]	4.47
Standard Error of the mean	(1.10)
95% Confidence Interval	2.76 to 7.24

[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 include terms for treatment, baseline LDL-C, study week and treatment by study week interaction.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	Reported p-value is multiplicity-adjusted. Hochberg procedure was used to adjust for multiple comparisons.
[4]	Other relevant estimation information:
	Ratio of odds of achieving pre-specified LDL-C level on EZ/Simva versus Atorva

Statistical Analysis 2 for Percentage of Patients Who Achieved LDL-C <100 mg/dL at Week 12

Groups [1]	Ezetimibe 10 mg/Simvastatin 20 mg vs. Atorvastatin 20 mg
Method [2]	Logistic Regression using GEE
P Value [3]	0.026
Ratio of odds [4]	1.77
Standard Error of the mean	(0.46)
95% Confidence Interval	1.07 to 2.94

[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 include terms for treatment, baseline LDL-C, study week and treatment by study week interaction.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	Reported p-value is multiplicity-adjusted. Hochberg procedure was used to adjust for multiple comparisons.
[4]	Other relevant estimation information:
	Ratio of odds of achieving pre-specified LDL-C level on EZ/Simva versus Atorva

Statistical Analysis 3 for Percentage of Patients Who Achieved LDL-C <100 mg/dL at Week 12

Groups [1]	Ezetimibe 10 mg/Simvastatin 40 mg vs. Atorva 40 mg
Method [2]	Logistic Regression using GEE
P Value [3]	0.017
Ratio of odds [4]	2.27
Standard Error of the mean	(0.71)
95% Confidence Interval	1.23 to 4.18

[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 include terms for treatment, baseline LDL-C, study week and treatment by study week interaction.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	Reported p-value is multiplicity-adjusted. Hochberg procedure was used to adjust for multiple comparisons.
[4]	Other relevant estimation information:
	Ratio of odds of achieving pre-specified LDL-C level on EZ/Simva versus Atorva

5. Secondary: Percentage of Patients With High Risk for CHD Who Achieved LDL-C <70 mg/dL at Week 12 [Time Frame: 12 Weeks]

Measure Type	Secondary
Measure Title	Percentage of Patients With High Risk for CHD Who Achieved LDL-C <70 mg/dL at Week 12
Measure Description	Risk was assessed utilizing a history of established CHD or CHD risk equivalent and Framingham Risk scoring.
Time Frame	12 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.
Patients with High Risk for CHD in the Full Analysis Set (FAS). The FAS population includes all randomized patients with baseline (BL) value and at least one valid after-BL value. After-BL measurements up to 3 days following the last dose of double-blind study medication were included in the analysis.

Reporting Groups

	Description
Atorvastatin 10 mg	Atorvastatin (Atorva) 10 mg once daily for 12 weeks
Ezetimibe 10 mg/Simvastatin 20 mg	Ezetimibe (EZ) 10 mg/simvastatin (Simva) 20 mg once daily for 12 weeks
Atorvastatin 20 mg	Atorvastatin 20 mg once daily for 12 weeks
Ezetimibe 10 mg/Simvastatin 40 mg	Ezetimibe 10 mg/simvastatin 40 mg once daily for 12 weeks
Atorva 40 mg	Atorvastatin 40 mg once daily for 12 weeks

Measured Values

	Atorvastatin 10 mg	Ezetimibe 10 mg/Simvastatin 20 mg	Atorvastatin 20 mg	Ezetimibe 10 mg/Simvastatin 40 mg	Atorva 40 mg
Number of Participants Analyzed [units: participants]	**138**	**138**	**128**	**130**	**136**
Percentage of Patients With High Risk for CHD Who Achieved LDL-C <70 mg/dL at Week 12 [units: Percent of Patients] Mean (Standard Error)	**10.9 (2.65)**	**54.3 (4.24)**	**28.9 (4.01)**	**69.2 (4.05)**	**38.2 (4.17)**

Statistical Analysis 1 for Percentage of Patients With High Risk for CHD Who Achieved LDL-C <70 mg/dL at Week 12

Groups [1]	Atorvastatin 10 mg vs. Ezetimibe 10 mg/Simvastatin 20 mg
Method [2]	Logistic Regression using GEE
P Value [3]	<0.001
Ratio of odds [4]	7.60
Standard Error of the mean	(2.20)
95% Confidence Interval	4.31 to 13.42

[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 include terms for treatment, baseline LDL-C, study week and treatment by study week interaction.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	Reported p-value is multiplicity-adjusted. Hochberg procedure was used to adjust for multiple comparisons.
[4]	Other relevant estimation information:
	Ratio of odds of achieving pre-specified LDL-C level on EZ/Simva versus Atorva

Statistical Analysis 2 for Percentage of Patients With High Risk for CHD Who Achieved LDL-C <70 mg/dL at Week 12

Groups [1]	Ezetimibe 10 mg/Simvastatin 20 mg vs. Atorvastatin 20 mg
Method [2]	Logistic Regression using GEE
P Value [3]	<0.001
Ratio of odds [4]	2.95
Standard Error of the mean	(0.69)
95% Confidence Interval	1.86 to 4.67

[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 include terms for treatment, baseline LDL-C, study week and treatment by study week interaction.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	Reported p-value is multiplicity-adjusted. Hochberg procedure was used to adjust for multiple comparisons.
[4]	Other relevant estimation information:
	Ratio of odds of achieving pre-specified LDL-C level on EZ/Simva versus Atorva

Statistical Analysis 3 for Percentage of Patients With High Risk for CHD Who Achieved LDL-C <70 mg/dL at Week 12

Groups [1]	Ezetimibe 10 mg/Simvastatin 40 mg vs. Atorva 40 mg
Method [2]	Logistic Regression using GEE
P Value [3]	<0.001
Ratio of odds [4]	2.15
Standard Error of the mean	(0.46)
95% Confidence Interval	1.42 to 3.27

[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 include terms for treatment, baseline LDL-C, study week and treatment by study week interaction.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	Reported p-value is multiplicity-adjusted. Hochberg procedure was used to adjust for multiple comparisons.
[4]	Other relevant estimation information:
	Ratio of odds of achieving pre-specified LDL-C level on EZ/Simva versus Atorva

6. Secondary: Percentage of Patients With AVD Who Achieved LDL-C <70 mg/dL at Week 12 [Time Frame: 12 Weeks]

Measure Type	Secondary
Measure Title	Percentage of Patients With AVD Who Achieved LDL-C <70 mg/dL at Week 12
Measure Description	Patients with AVD Who Achieved LDL-C <70 mg/dL. AVD was defined as a history of myocardial infarction, stable angina, coronary artery procedures or evidence of clinically significant myocardial ischemia.
Time Frame	12 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.
Patients with AVD in the Full Analysis Set (FAS). The FAS population includes all randomized patients with baseline (BL) value and at least one valid after-BL value. After-BL measurements up to 3 days following the last dose of double-blind study medication were included in the analysis.

Reporting Groups

	Description
Atorvastatin 10 mg	Atorvastatin (Atorva) 10 mg once daily for 12 weeks
Ezetimibe 10 mg/Simvastatin 20 mg	Ezetimibe (EZ) 10 mg/simvastatin (Simva) 20 mg once daily for 12 weeks
Atorvastatin 20 mg	Atorvastatin 20 mg once daily for 12 weeks
Ezetimibe 10 mg/Simvastatin 40 mg	Ezetimibe 10 mg/simvastatin 40 mg once daily for 12 weeks
Atorva 40 mg	Atorvastatin 40 mg once daily for 12 weeks

Measured Values

	Atorvastatin 10 mg	Ezetimibe 10 mg/Simvastatin 20 mg	Atorvastatin 20 mg	Ezetimibe 10 mg/Simvastatin 40 mg	Atorva 40 mg
Number of Participants Analyzed [units: participants]	**70**	**81**	**79**	**79**	**72**
Percentage of Patients With AVD Who Achieved LDL-C <70 mg/dL at Week 12 [units: Percent of Patients] Mean (Standard Error)	**10.0 (3.59)**	**44.4 (5.52)**	**31.6 (5.23)**	**65.8 (5.34)**	**44.4 (5.86)**

Statistical Analysis 1 for Percentage of Patients With AVD Who Achieved LDL-C <70 mg/dL at Week 12

Groups [1]	Atorvastatin 10 mg vs. Ezetimibe 10 mg/Simvastatin 20 mg
Method [2]	Logistic Regression using GEE
P Value [3]	<0.001
Ratio of odds [4]	6.02
Standard Error of the mean	(2.45)
95% Confidence Interval	2.71 to 13.38

[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 include terms for treatment, baseline LDL-C, study week and treatment by study week interaction.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	Reported p-value is multiplicity-adjusted. Hochberg procedure was used to adjust for multiple comparisons.
[4]	Other relevant estimation information:
	Ratio of odds of achieving pre-specified LDL-C level on EZ/Simva versus Atorva

Statistical Analysis 2 for Percentage of Patients With AVD Who Achieved LDL-C <70 mg/dL at Week 12

Groups [1]	Ezetimibe 10 mg/Simvastatin 20 mg vs. Atorvastatin 20 mg
Method [2]	Logistic Regression using GEE
P Value [3]	0.069

Ratio of odds [4]	1.67
Standard Error of the mean	(0.47)
95% Confidence Interval	0.96 to 2.60

[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 include terms for treatment, baseline LDL-C, study week and treatment by study week interaction.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	Reported p-value is multiplicity-adjusted. Hochberg procedure was used to adjust for multiple comparisons.
[4]	Other relevant estimation information:
	Ratio of odds of achieving pre-specified LDL-C level on EZ/Simva versus Atorva

Statistical Analysis 3 for Percentage of Patients With AVD Who Achieved LDL-C <70 mg/dL at Week 12

Groups [1]	Ezetimibe 10 mg/Simvastatin 40 mg vs. Atorva 40 mg
Method [2]	Logistic Regression using GEE
P Value [3]	0.039
Ratio of odds [4]	1.78
Standard Error of the mean	(0.44)
95% Confidence Interval	1.10 to 2.90

[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 include terms for treatment, baseline LDL-C, study week and treatment by study week interaction.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	Reported p-value is multiplicity-adjusted. Hochberg procedure was used to adjust for multiple comparisons.
[4]	Other relevant estimation information:
	Ratio of odds of achieving pre-specified LDL-C level on EZ/Simva versus Atorva

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	No text entered.
Additional Description	AE reporting is based on number of subjects at risk. Subjects at risk are randomized subjects who received at least one dose of study drug. Five patients where excluded from the randomized population because they did not receive one dose of study drug (EZ/Simva 20 mg - 3 patients; Atorva 20 mg - 1 patient; Atorva 40 mg - 1 patient).

Reporting Groups

	Description
Atorvastatin 10 mg	Atorvastatin (Atorva) 10 mg once daily for 12 weeks
Ezetimibe 10 mg/Simvastatin 20 mg	Ezetimibe (EZ) 10 mg/simvastatin (Simva) 20 mg once daily for 12 weeks
Atorvastatin 20 mg	Atorvastatin 20 mg once daily for 12 weeks
Ezetimibe 10 mg/Simvastatin 40 mg	Ezetimibe 10 mg/simvastatin 40 mg once daily for 12 weeks
Atorvastatin 40 mg	Atorvastatin 40 mg once daily for 12 weeks

Serious Adverse Events

	Atorvastatin 10 mg	Ezetimibe 10 mg/Simvastatin 20 mg	Atorvastatin 20 mg	Ezetimibe 10 mg/Simvastatin 40 mg	Atorvastatin 40 mg
Total, serious adverse events					
# participants affected / at risk	**4/257 (1.56%)**	**8/256 (3.13%)**	**3/258 (1.16%)**	**3/257 (1.17%)**	**5/256 (1.95%)**
Cardiac disorders					
AV dissociation *					
# participants affected / at risk	**0/257 (0.00%)**	**1/256 (0.39%)**	**0/258 (0.00%)**	**0/257 (0.00%)**	**0/256 (0.00%)**
Acute myocardial infarction *					
# participants affected / at risk	**1/257 (0.39%)**	**2/256 (0.78%)**	**0/258 (0.00%)**	**0/257 (0.00%)**	**0/256 (0.00%)**
Myocardial infarction *					
# participants affected / at risk	**0/257 (0.00%)**	**0/256 (0.00%)**	**0/258 (0.00%)**	**2/257 (0.78%)**	**0/256 (0.00%)**
Ventricular fibrillation *					
# participants affected / at risk	**0/257 (0.00%)**	**0/256 (0.00%)**	**1/258 (0.39%)**	**0/257 (0.00%)**	**0/256 (0.00%)**
Gastrointestinal disorders					
Abdominal pain *					
# participants affected / at risk	**0/257 (0.00%)**	**0/256 (0.00%)**	**0/258 (0.00%)**	**0/257 (0.00%)**	**1/256 (0.39%)**
Abdominal strangulated hernia *					
# participants affected / at risk	**0/257 (0.00%)**	**0/256 (0.00%)**	**1/258 (0.39%)**	**0/257 (0.00%)**	**0/256 (0.00%)**
Colitis ischaemic *					
# participants affected / at risk	**0/257 (0.00%)**	**1/256 (0.39%)**	**0/258 (0.00%)**	**0/257 (0.00%)**	**0/256 (0.00%)**
Diverticulum intestinal *					
# participants affected / at risk	**0/257 (0.00%)**	**1/256 (0.39%)**	**0/258 (0.00%)**	**0/257 (0.00%)**	**0/256 (0.00%)**
Gastrointestinal haemorrhage *					
# participants affected / at risk	**0/257 (0.00%)**	**1/256 (0.39%)**	**0/258 (0.00%)**	**0/257 (0.00%)**	**0/256 (0.00%)**

General disorders					
Mechanical complication of implant *					
# participants affected / at risk	**1/257 (0.39%)**	**0/256 (0.00%)**	**0/258 (0.00%)**	**0/257 (0.00%)**	**0/256 (0.00%)**
Oedema peripheral *					
# participants affected / at risk	**0/257 (0.00%)**	**0/256 (0.00%)**	**0/258 (0.00%)**	**0/257 (0.00%)**	**1/256 (0.39%)**
Infections and infestations					
Pneumonia *					
# participants affected / at risk	**0/257 (0.00%)**	**0/256 (0.00%)**	**0/258 (0.00%)**	**1/257 (0.39%)**	**0/256 (0.00%)**
Urinary tract infection *					
# participants affected / at risk	**0/257 (0.00%)**	**0/256 (0.00%)**	**0/258 (0.00%)**	**0/257 (0.00%)**	**1/256 (0.39%)**
Injury, poisoning and procedural complications					
Femur fracture *					
# participants affected / at risk	**0/257 (0.00%)**	**0/256 (0.00%)**	**0/258 (0.00%)**	**0/257 (0.00%)**	**1/256 (0.39%)**
Head injury *					
# participants affected / at risk	**0/257 (0.00%)**	**0/256 (0.00%)**	**1/258 (0.39%)**	**0/257 (0.00%)**	**0/256 (0.00%)**
Hip fracture *					
# participants affected / at risk	**0/257 (0.00%)**	**1/256 (0.39%)**	**0/258 (0.00%)**	**0/257 (0.00%)**	**0/256 (0.00%)**
Meniscus lesion *					
# participants affected / at risk	**0/257 (0.00%)**	**0/256 (0.00%)**	**0/258 (0.00%)**	**0/257 (0.00%)**	**1/256 (0.39%)**
Soft tissue injury *					
# participants affected / at risk	**0/257 (0.00%)**	**0/256 (0.00%)**	**1/258 (0.39%)**	**0/257 (0.00%)**	**0/256 (0.00%)**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
Bladder cancer *					
# participants affected / at risk	**0/257 (0.00%)**	**1/256 (0.39%)**	**0/258 (0.00%)**	**0/257 (0.00%)**	**0/256 (0.00%)**
Melanocytic naevus *					
# participants affected / at risk	**1/257 (0.39%)**	**0/256 (0.00%)**	**0/258 (0.00%)**	**0/257 (0.00%)**	**0/256 (0.00%)**
Sarcoma *					
# participants affected / at risk	**1/257 (0.39%)**	**0/256 (0.00%)**	**0/258 (0.00%)**	**0/257 (0.00%)**	**0/256 (0.00%)**
Psychiatric disorders					
Panic attack *					
# participants affected / at risk	**0/257 (0.00%)**	**0/256 (0.00%)**	**0/258 (0.00%)**	**0/257 (0.00%)**	**1/256 (0.39%)**

Respiratory, thoracic and mediastinal disorders					
Intervertebral disc protrusion *					
# participants affected / at risk	**0/257 (0.00%)**	**1/256 (0.39%)**	**0/258 (0.00%)**	**0/257 (0.00%)**	**0/256 (0.00%)**
Pickwickian syndrome *					
# participants affected / at risk	**0/257 (0.00%)**	**0/256 (0.00%)**	**0/258 (0.00%)**	**0/257 (0.00%)**	**1/256 (0.39%)**
Pulmonary oedema *					
# participants affected / at risk	**1/257 (0.39%)**	**0/256 (0.00%)**	**0/258 (0.00%)**	**0/257 (0.00%)**	**0/256 (0.00%)**

* Events were collected by non-systematic assessment

Other Adverse Events

Hide Other Adverse Events

Time Frame	No text entered.
Additional Description	AE reporting is based on number of subjects at risk. Subjects at risk are randomized subjects who received at least one dose of study drug. Five patients where excluded from the randomized population because they did not receive one dose of study drug (EZ/Simva 20 mg - 3 patients; Atorva 20 mg - 1 patient; Atorva 40 mg - 1 patient).

Frequency Threshold

Threshold above which other adverse events are reported	1%

Reporting Groups

	Description
Atorvastatin 10 mg	Atorvastatin (Atorva) 10 mg once daily for 12 weeks
Ezetimibe 10 mg/Simvastatin 20 mg	Ezetimibe (EZ) 10 mg/simvastatin (Simva) 20 mg once daily for 12 weeks
Atorvastatin 20 mg	Atorvastatin 20 mg once daily for 12 weeks
Ezetimibe 10 mg/Simvastatin 40 mg	Ezetimibe 10 mg/simvastatin 40 mg once daily for 12 weeks
Atorvastatin 40 mg	Atorvastatin 40 mg once daily for 12 weeks

Other Adverse Events

	Atorvastatin 10 mg	**Ezetimibe 10 mg/Simvastatin 20 mg**	**Atorvastatin 20 mg**	**Ezetimibe 10 mg/Simvastatin 40 mg**	**Atorvastatin 40 mg**
Total, other (not including serious) adverse events					
# participants affected / at risk	**26/257 (10.12%)**	**32/256 (12.50%)**	**26/258 (10.08%)**	**32/257 (12.45%)**	**30/256 (11.72%)**
Gastrointestinal disorders					
Constipation *					
# participants affected / at risk	**3/257 (1.17%)**	**0/256 (0.00%)**	**0/258 (0.00%)**	**4/257 (1.56%)**	**5/256 (1.95%)**

Diarrhoea *					
# participants affected / at risk	**3/257 (1.17%)**	**1/256 (0.39%)**	**1/258 (0.39%)**	**4/257 (1.56%)**	**3/256 (1.17%)**
Infections and infestations					
Bronchitis *					
# participants affected / at risk	**1/257 (0.39%)**	**2/256 (0.78%)**	**4/258 (1.55%)**	**4/257 (1.56%)**	**4/256 (1.56%)**
Nasopharyngitis *					
# participants affected / at risk	**2/257 (0.78%)**	**5/256 (1.95%)**	**4/258 (1.55%)**	**3/257 (1.17%)**	**2/256 (0.78%)**
Urinary tract infection *					
# participants affected / at risk	**2/257 (0.78%)**	**2/256 (0.78%)**	**4/258 (1.55%)**	**0/257 (0.00%)**	**3/256 (1.17%)**
Investigations					
Aspartate aminotransferase increased *					
# participants affected / at risk	**0/257 (0.00%)**	**2/256 (0.78%)**	**0/258 (0.00%)**	**4/257 (1.56%)**	**3/256 (1.17%)**
Musculoskeletal and connective tissue disorders					
Arthralgia *					
# participants affected / at risk	**3/257 (1.17%)**	**1/256 (0.39%)**	**3/258 (1.16%)**	**4/257 (1.56%)**	**2/256 (0.78%)**
Back pain *					
# participants affected / at risk	**5/257 (1.95%)**	**2/256 (0.78%)**	**3/258 (1.16%)**	**4/257 (1.56%)**	**4/256 (1.56%)**
Muscle spasms *					
# participants affected / at risk	**1/257 (0.39%)**	**4/256 (1.56%)**	**4/258 (1.55%)**	**1/257 (0.39%)**	**1/256 (0.39%)**
Myalgia *					
# participants affected / at risk	**5/257 (1.95%)**	**3/256 (1.17%)**	**3/258 (1.16%)**	**2/257 (0.78%)**	**3/256 (1.17%)**
Nervous system disorders					
Dizziness *					
# participants affected / at risk	**2/257 (0.78%)**	**6/256 (2.34%)**	**0/258 (0.00%)**	**2/257 (0.78%)**	**3/256 (1.17%)**
Headache *					
# participants affected / at risk	**1/257 (0.39%)**	**5/256 (1.95%)**	**3/258 (1.16%)**	**3/257 (1.17%)**	**2/256 (0.78%)**
Vascular disorders					
Hypertension *					
# participants affected / at risk	**1/257 (0.39%)**	**3/256 (1.17%)**	**1/258 (0.39%)**	**3/257 (1.17%)**	**1/256 (0.39%)**

* Events were collected by non-systematic assessment

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.

Results Point of Contact:

Name/Title: Senior Vice President, Global Clinical Development
Organization: Merck Sharp & Dohme Corp
phone: 1-800-672-6372
e-mail: ClinicalTrialsDisclosure@merck.com

Publications of Results:

Foody JM, Brown WV, Zieve F, Adewale AJ, Flaim D, Lowe RS, Jones-Burton C, Tershakovec AM. Safety and efficacy of ezetimibe/simvastatin combination versus atorvastatin alone in adults ≥65 years of age with hypercholesterolemia and with or at moderately high/high risk for coronary heart disease (the VYTELD study). Am J Cardiol. 2010 Nov 1;106(9):1255-63. doi: 10.1016/j.amjcard.2010.06.051.

Responsible Party:	Merck Sharp & Dohme Corp.
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