Ezetimibe/Simvastatin in Patients With Metabolic Syndrome (0653A-107)(COMPLETED)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

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

ClinicalTrials.gov Identifier:
NCT00409773

First received: December 8, 2006
Last updated: September 2, 2015
Last verified: September 2015
History of Changes

Purpose

A 6-week clinical trial in patients with metabolic syndrome and hypercholesterolemia at high risk for coronary heart disease to study the effects of ezetimibe/simvastatin and atorvastatin on lipids.

Condition	Intervention	Phase
Hypercholesterolemia Metabolic Syndrome	Drug: ezetimibe (+) simvastatin Drug: Comparator: atorvastatin 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 Multicenter, Randomized, Double-Blind, Parallel Arm, 6-Week Study to Evaluate the Efficacy and Safety of Ezetimibe/Simvastatin Versus Atorvastatin in Patients With Metabolic Syndrome and Hypercholesterolemia at High Risk for Coronary Heart Disease

Resource links provided by NLM:

MedlinePlus related topics: Cholesterol Metabolic Syndrome

Drug Information available for: Simvastatin Atorvastatin Atorvastatin calcium Ezetimibe

Genetic and Rare Diseases Information Center resources: Abdominal Obesity Metabolic Syndrome

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 6 [Time Frame: Baseline and 6 Weeks] [Designated as safety issue: No]

Secondary Outcome Measures:

- Percent Change From Baseline in Total Cholesterol(mg/dL) at Week 6 [Time Frame: Baseline and 6 Weeks] [Designated as safety issue: No]
- Percent Change From Baseline in Triglyceride (TG) (mg/dL) at Week 6 [Time Frame: Baseline and 6 Weeks] [Designated as safety issue: No]
- Percent Change From Baseline in High Density Lipoprotein Cholesterol (HDL-C) at Week 6 [Time Frame: Baseline and 6 Weeks] [Designated as safety issue: No]
- Percent Change From Baseline in Non- High Density Lipoprotein Cholesterol (Non-HDL-C) at Week 6 [Time Frame: Baseline and 6 Weeks] [Designated as safety issue: No]
- Percent Change From Baseline in Very Low Density Lipoprotein Cholesterol (VLDL-C) at Week 6 [Time Frame: Baseline and 6 Weeks] [Designated as safety issue: No]
- Percent Change From Baseline in Apolipoprotein- B (Apo-B) at Week 6 [Time Frame: Baseline and 6 Weeks] [Designated as safety issue: No]
- Percent Change From Baseline in Apolipoprotein-A1 (Apo-A1) at Week 6 [Time Frame: Baseline and 6 Weeks] [Designated as safety issue: No]
- Percent Change From Baseline in Total-Cholesterol: High Density Lipoprotein-Cholesterol (Total-C:HDL- C) at Week 6 [Time Frame: Baseline and 6 Weeks] [Designated as safety issue: No]
- Percent Change From Baseline in Low Density Lipoprotein Cholesterol: High Density Lipoprotein Cholesterol (LDL-C: HDL-C) at Week 6 [Time Frame: Baseline and 6 Weeks] [Designated as safety issue: No]
- Percent Change From Baseline in Apolipoprotein-B: Apolipoprotein-A1 (Apo-B:Apo-A1) at Week 6 [Time Frame: Baseline and 6 weeks] [Designated as safety issue: No]
- Percent Change From Baseline in Non-High Density Lipoprotein Cholesterol: High Density Lipoprotein Cholesterol (Non-HDL-C:HDL-C) at Week 6 [Time Frame: Baseline and 6 Weeks] [Designated as safety issue: No]
- Percent Change From Baseline in Low Density Lipoprotein Cholesterol (LDL-C) at Week 6 in Patients With Atherosclerotic Vascular Disease (AVD) [Time Frame: Baseline and 6 Weeks] [Designated as safety issue: No]
- Percent Change From Baseline in Low Density Lipoprotein Cholesterol (LDL-C) at Week 6 in Patients Without Atherosclerotic Vascular Disease (AVD) [Time Frame: Baseline and 6 Weeks] [Designated as safety issue: No]
- Percent Change From Baseline in High-Sensitivity C-reactive (Hs-CRP) (mg/dL) at Week 6 [Time Frame: Baseline and 6 Weeks] [Designated as safety issue: No]

Enrollment:	1143
Study Start Date:	January 2007
Study Completion Date:	July 2008
Primary Completion Date:	July 2008 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
1 Arm 1: drug + comparator + Placebo	Drug: ezetimibe (+) simvastatin Ezetimibe (+) simvastatin combination tablet at doses of 10/20 mg or 10/40 mg. Other Names: • MK0653A • Vytorin® Drug: Comparator: atorvastatin calcium Atorvastatin will be supplied in 10mg, 20mg and 40mg tablets. Each patient will receive 1 active treatment dose & 2 Placebo doses at randomization according to a predetermined partial blinding schedule to reduce the number of pills from 5 to 3 per patient per day for 6 weeks. Other Name: Lipitor ® Drug: Comparator: Placebo (unspecified) Atorvastatin Placebo will be supplied in 10mg, 20mg and 40mg tablets. ezetimibe/simvastatin Placebo will be supplied in 10/20mg and 10/40mg combination tablets.

	Each patient will receive 1 active treatment dose & 2 Placebo doses at randomization according to a predetermined partial blinding schedule to reduce the number of pills from 5 to 3 per patient per day for 6 weeks.
2 Arm 2: drug + comparator + Placebo	Drug: ezetimibe (+) simvastatin Ezetimibe (+) simvastatin combination tablet at doses of 10/20 mg or 10/40 mg. Other Names: • MK0653A • Vytorin® Drug: Comparator: atorvastatin calcium Atorvastatin will be supplied in 10mg, 20mg and 40mg tablets. Each patient will receive 1 active treatment dose & 2 Placebo doses at randomization according to a predetermined partial blinding schedule to reduce the number of pills from 5 to 3 per patient per day for 6 weeks. Other Name: Lipitor ® Drug: Comparator: Placebo (unspecified) Atorvastatin Placebo will be supplied in 10mg, 20mg and 40mg tablets. ezetimibe/simvastatin Placebo will be supplied in 10/20mg and 10/40mg combination tablets. Each patient will receive 1 active treatment dose & 2 Placebo doses at randomization according to a predetermined partial blinding schedule to reduce the number of pills from 5 to 3 per patient per day for 6 weeks.
3 Arm 3: drug + comparator + Placebo	Drug: ezetimibe (+) simvastatin Ezetimibe (+) simvastatin combination tablet at doses of 10/20 mg or 10/40 mg. Other Names: • MK0653A • Vytorin® Drug: Comparator: atorvastatin calcium Atorvastatin will be supplied in 10mg, 20mg and 40mg tablets. Each patient will receive 1 active treatment dose & 2 Placebo doses at randomization according to a predetermined partial blinding schedule to reduce the number of pills from 5 to 3 per patient per day for 6 weeks. Other Name: Lipitor ® Drug: Comparator: Placebo (unspecified) Atorvastatin Placebo will be supplied in 10mg, 20mg and 40mg tablets. ezetimibe/simvastatin Placebo will be supplied in 10/20mg and 10/40mg combination tablets. Each patient will receive 1 active treatment dose & 2 Placebo doses at randomization according to a predetermined partial blinding schedule to reduce the number of pills from 5 to 3 per patient per day for 6 weeks.
4 Arm 4: drug + comparator + Placebo	Drug: ezetimibe (+) simvastatin Ezetimibe (+) simvastatin combination tablet at doses of 10/20 mg or 10/40 mg. Other Names: • MK0653A • Vytorin® Drug: Comparator: atorvastatin calcium Atorvastatin will be supplied in 10mg, 20mg and 40mg tablets. Each patient will receive 1 active treatment dose & 2 Placebo doses at randomization according to a predetermined partial blinding schedule to reduce the number of pills from 5 to 3 per patient per day for 6 weeks. Other Name: Lipitor ® Drug: Comparator: Placebo (unspecified) Atorvastatin Placebo will be supplied in 10mg, 20mg and 40mg tablets. ezetimibe/simvastatin Placebo will be supplied in 10/20mg and 10/40mg combination tablets. Each patient will receive 1 active treatment dose & 2 Placebo doses at randomization according to a predetermined partial blinding schedule to reduce the number of pills from 5 to 3 per patient per day for 6 weeks.
5 Arm 5: drug +	Drug: ezetimibe (+) simvastatin Ezetimibe (+) simvastatin combination tablet at doses of 10/20 mg or 10/40 mg.

comparator + Placebo	Other Names: • MK0653A • Vytorin® Drug: Comparator: atorvastatin calcium Atorvastatin will be supplied in 10mg, 20mg and 40mg tablets. Each patient will receive 1 active treatment dose & 2 Placebo doses at randomization according to a predetermined partial blinding schedule to reduce the number of pills from 5 to 3 per patient per day for 6 weeks. Other Name: Lipitor ® Drug: Comparator: Placebo (unspecified) Atorvastatin Placebo will be supplied in 10mg, 20mg and 40mg tablets. ezetimibe/simvastatin Placebo will be supplied in 10/20mg and 10/40mg combination tablets. Each patient will receive 1 active treatment dose & 2 Placebo doses at randomization according to a predetermined partial blinding schedule to reduce the number of pills from 5 to 3 per patient per day for 6 weeks.

Eligibility

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

Criteria

Inclusion Criteria:

- Patients 18 to 79 years of age with metabolic syndrome and hypercholesterolemia at high risk for coronary heart disease (CHD) with LDL-C above 70 mg/dL or 100 mg/dL depending on their CHD risk category

Exclusion Criteria:

- A condition which, in the opinion of the investigator, pose a risk to the patient or interfere with participating in the study
- Patient is likely to be greater than 20% noncompliant in taking study medications
- Patients with chronic medical conditions
- Patients with unstable doses of medications
- Pregnant or lactating women, women intending to become pregnant
- Patient is currently receiving prescription therapy with statins or other lipid-altering medications
- Patient with Type 1 or Type 2 diabetes mellitus that is poorly controlled, newly diagnosed, or is taking new or recently adjusted antidiabetic pharmacotherapy (with the exception of +/- 10 units of insulin)

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: NCT00409773

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)

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

No publications provided by Merck Sharp & Dohme Corp.

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

Rosen JB, Ballantyne CM, Hsueh WA, Lin J, Shah AK, Lowe RS, Tershakovec AM. Influence of metabolic syndrome factors and insulin resistance on the efficacy of ezetimibe/simvastatin and atorvastatin in patients with metabolic syndrome and atherosclerotic coronary heart disease risk. Lipids Health Dis. 2015 Sep 4;14:103. doi: 10.1186/s12944-015-0075-5.

Robinson JG, Ballantyne CM, Hsueh W, Rosen J, Lin J, Shah A, Lowe RS, Hanson ME, Tershakovec AM. Achievement of specified low-density lipoprotein cholesterol, non-high-density lipoprotein cholesterol apolipoprotein B, and high-sensitivity C-reactive protein levels with ezetimibe/simvastatin or atorvastatin in metabolic syndrome patients with and without atherosclerotic vascular disease (from the VYMET study). J Clin Lipidol. 2011 Nov-Dec;5(6):474-82. doi: 10.1016/j.jacl.2011.06.004. Epub 2011 Jun 15.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00409773 History of Changes
Other Study ID Numbers:	**0653A-107** 2006_527
Study First Received:	December 8, 2006
Results First Received:	June 16, 2009
Last Updated:	September 2, 2015
Health Authority:	United States: Food and Drug Administration

Additional relevant MeSH terms:

Hypercholesterolemia	Atorvastatin
Metabolic Syndrome X	Ezetimibe
Syndrome	Simvastatin
Disease	Anticholesteremic Agents
Dyslipidemias	Antimetabolites
Glucose Metabolism Disorders	Enzyme Inhibitors
Hyperinsulinism	Hydroxymethylglutaryl-CoA Reductase Inhibitors
Hyperlipidemias	Hypolipidemic Agents
Insulin Resistance	Lipid Regulating Agents
Lipid Metabolism Disorders	Molecular Mechanisms of Pharmacological Action
Metabolic Diseases	Pharmacologic Actions
Pathologic Processes	Therapeutic Uses

ClinicalTrials.gov processed this record on March 30, 2016

TO TOP

For Patients and Families | For Researchers | For Study Record Managers

HOME RSS FEEDS SITE MAP TERMS AND CONDITIONS DISCLAIMER CONTACT NLM HELP DESK

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First received: December 8, 2006
Last updated: September 2, 2015
Last verified: September 2015
History of Changes

Results First Received: June 16, 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
Conditions:	Hypercholesterolemia Metabolic Syndrome
Interventions:	Drug: ezetimibe (+) simvastatin Drug: Comparator: atorvastatin 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 III

First Patient In 06-Feb-2007:; Last Patient Last Visit 16-Jul-2008

110 centers worldwide (International, 12 countries)

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.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
Patients were randomized to 1 of 5 treatment groups: ezetimibe/simvastatin combination tablet or atorvastatin alone for 6 weeks stratified according to their baseline risk category stratum (high risk patients with atherosclerotic vascular disease or high risk patients without atherosclerotic vascular disease and moderately high risk patients).

Reporting Groups

	Description
Atorva 10 mg	Atorvastatin 10 mg once daily for 6 weeks
EZ/Simva 10 mg/20 mg	Ezetimibe (+) simvastatin combination tablet at doses of 10/20 mg
Atorva 20mg	Atorvastatin 20 mg once daily for 6 weeks
EZ/Simva 10 mg/40 mg	Ezetimibe (+) simvastatin combination tablet at doses of 10/40 mg
Atorva 40 mg	Atorvastatin 40 mg once daily for 6 weeks

Participant Flow: Overall Study

	Atorva 10 mg	EZ/Simva 10 mg/20 mg	Atorva 20mg	EZ/Simva 10 mg/40 mg	Atorva 40 mg
STARTED	**229**	**229**	**229**	**228**	**228**
COMPLETED	**220**	**222**	**220**	**216**	**218**
NOT COMPLETED	**9**	**7**	**9**	**12**	**10**
Adverse Event	**3**	**4**	**4**	**2**	**6**
Lost to Follow-up	**6**	**1**	**2**	**3**	**1**
Physician Decision	**0**	**0**	**0**	**2**	**0**
Protocol Violation	**0**	**2**	**3**	**3**	**1**
Withdrawal by Subject	**0**	**0**	**0**	**2**	**1**
Lack of Eligibility	**0**	**0**	**0**	**0**	**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
Atorva 10 mg	Atorvastatin 10 mg once daily for 6 weeks
EZ/Simva 10 mg/20 mg	Ezetimibe (+) simvastatin combination tablet at doses of 10/20 mg
Atorva 20mg	Atorvastatin 20 mg once daily for 6 weeks

EZ/Simva 10 mg/40 mg	Ezetimibe (+) simvastatin combination tablet at doses of 10/40 mg
Atorva 40 mg	Atorvastatin 40 mg once daily for 6 weeks
Total	Total of all reporting groups

Baseline Measures

	Atorva 10 mg	EZ/Simva 10 mg/20 mg	Atorva 20mg	EZ/Simva 10 mg/40 mg	Atorva 40 mg	Total
Number of Participants [units: participants]	**229**	**229**	**229**	**228**	**228**	**1143**
Age [units: years] Mean (Full Range)	**59.7 (31 to 79)**	**59.7 (32 to 78)**	**58.2 (33 to 78)**	**59.5 (28 to 80)**	**58.4 (28 to 79)**	**59.1 (28 to 80)**
Gender [units: participants]						
Female	**97**	**87**	**106**	**104**	**104**	**498**
Male	**132**	**142**	**123**	**124**	**124**	**645**
Race/Ethnicity, Customized [units: participants]						
Asian	**17**	**15**	**15**	**18**	**21**	**86**
Black	**13**	**18**	**18**	**12**	**14**	**75**
Other	**27**	**27**	**19**	**27**	**26**	**126**
White	**172**	**169**	**177**	**171**	**167**	**856**

Outcome Measures

Hide All Outcome Measures

1. Primary: Percent Change From Baseline in Low Density Lipoprotein (LDL-C) at Week 6 [Time Frame: Baseline and 6 Weeks]

Measure Type	Primary
Measure Title	Percent Change From Baseline in Low Density Lipoprotein (LDL-C) at Week 6
Measure Description	No text entered.
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 patients who took at least 1 dose of study medication and had a baseline (BL) value and at least one post BL value. Post BL measurements up to 3 days following the last dose of double-blind study medication were included in the analysis.

Reporting Groups

	Description
Atorva 10 mg	Atorvastatin 10 mg once daily for 6 weeks
EZ/Simva 10 mg/20 mg	Ezetimibe (+) simvastatin combination tablet at doses of 10/20 mg
Atorva 20mg	Atorvastatin 20 mg once daily for 6 weeks
EZ/Simva 10 mg/40 mg	Ezetimibe (+) simvastatin combination tablet at doses of 10/40 mg
Atorva 40 mg	Atorvastatin 40 mg once daily for 6 weeks

Measured Values

	Atorva 10 mg	EZ/Simva 10 mg/20 mg	Atorva 20mg	EZ/Simva 10 mg/40 mg	Atorva 40 mg
Number of Participants Analyzed [units: participants]	**215**	**219**	**215**	**217**	**217**
Percent Change From Baseline in Low Density Lipoprotein (LDL-C) at Week 6 [units: Percent Change] Least Squares Mean (95% Confidence Interval)	**-36.5 (-38.9 to -34.0)**	**-49.6 (-52.0 to -47.2)**	**-39.4 (-41.8 to -36.9)**	**-53.9 (-56.4 to -51.5)**	**-46.0 (-48.4 to -43.6)**

Statistical Analysis 1 for Percent Change From Baseline in Low Density Lipoprotein (LDL-C) at Week 6

Groups [1]	Atorva 10 mg vs. EZ/Simva 10 mg/20 mg
Method [2]	ANOVA
P Value [3]	<0.001
Mean Difference (Final Values) [4]	-13.1
Standard Error of the mean	(1.7)
95% Confidence Interval	-16.5 to -9.8

[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:
	ANOVA with terms for treatment and baseline risk stratum
[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 6

Groups [1]	EZ/Simva 10 mg/20 mg vs. Atorva 20mg
Method [2]	ANOVA
P Value [3]	<0.001

Mean Difference (Final Values) [4]	-10.2
Standard Error of the mean	(1.7)
95% Confidence Interval	-13.6 to -6.9

[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 with terms for treatment and baseline risk stratum
[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 6

Groups [1]	EZ/Simva 10 mg/40 mg vs. Atorva 40 mg
Method [2]	ANOVA
P Value [3]	<0.001
Mean Difference (Final Values) [4]	-8.0
Standard Error of the mean	(1.7)
95% Confidence Interval	-11.3 to -4.6

[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 with terms for treatment and baseline risk stratum
[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: Percent Change From Baseline in Total Cholesterol(mg/dL) at Week 6 [Time Frame: Baseline and 6 Weeks]

Measure Type	Secondary
Measure Title	Percent Change From Baseline in Total Cholesterol(mg/dL) at Week 6
Measure Description	No text entered.
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 patients who took at least 1 dose of study medication and had a baseline (BL) value and at least one post BL value. Post BL measurements up to 3 days following the last dose of double-blind study medication were included in the analysis.

Reporting Groups

	Description
Atorva 10 mg	Atorvastatin 10 mg once daily for 6 weeks
EZ/Simva 10 mg/20 mg	Ezetimibe (+) simvastatin combination tablet at doses of 10/20 mg
Atorva 20mg	Atorvastatin 20 mg once daily for 6 weeks
EZ/Simva 10 mg/40 mg	Ezetimibe (+) simvastatin combination tablet at doses of 10/40 mg
Atorva 40 mg	Atorvastatin 40 mg once daily for 6 weeks

Measured Values

	Atorva 10 mg	**EZ/Simva 10 mg/20 mg**	**Atorva 20mg**	**EZ/Simva 10 mg/40 mg**	**Atorva 40 mg**
Number of Participants Analyzed [units: participants]	**215**	**220**	**216**	**217**	**218**
Percent Change From Baseline in Total Cholesterol(mg/dL) at Week 6 [units: Percent Change] Least Squares Mean (95% Confidence Interval)	**-26.5 (-28.2 to -24.7)**	**-33.7 (-35.4 to -31.9)**	**-28.3 (-30.1 to -26.6)**	**-37.3 (-39.0 to -35.5)**	**-32.8 (-34.6 to -31.1)**

Statistical Analysis 1 for Percent Change From Baseline in Total Cholesterol(mg/dL) at Week 6

Groups [1]	Atorva 10 mg vs. EZ/Simva 10 mg/20 mg
Method [2]	ANOVA
P Value [3]	<0.001
Mean Difference (Final Values) [4]	-7.2
Standard Error of the mean	(1.2)
95% Confidence Interval	-9.6 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:
	ANOVA with terms for treatment and baseline risk stratum
[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 Percent Change From Baseline in Total Cholesterol(mg/dL) at Week 6

Groups [1]	EZ/Simva 10 mg/20 mg vs. Atorva 20mg
Method [2]	ANOVA
P Value [3]	<0.001
Mean Difference (Final Values) [4]	-5.4
Standard Error of the mean	(1.2)
95% Confidence Interval	-7.8 to -2.9

[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 with terms for treatment and baseline risk stratum
[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 3 for Percent Change From Baseline in Total Cholesterol(mg/dL) at Week 6

Groups [1]	EZ/Simva 10 mg/40 mg vs. Atorva 40 mg
Method [2]	ANOVA
P Value [3]	<0.001
Mean Difference (Final Values) [4]	-4.4
Standard Error of the mean	(1.2)
95% Confidence Interval	-6.8 to -2.0

[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:
	ANOVA with terms for treatment and baseline risk stratum
[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. Secondary: Percent Change From Baseline in Triglyceride (TG) (mg/dL) at Week 6 [Time Frame: Baseline and 6 Weeks]

Measure Type	Secondary
Measure Title	Percent Change From Baseline in Triglyceride (TG) (mg/dL) at Week 6
Measure Description	No text entered.
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 patients who took at least 1 dose of study medication and had a baseline (BL) value and at least one post BL value. Post BL measurements up to 3 days following the last dose of double-blind study medication were included in the analysis.

Reporting Groups

	Description
Atorva 10 mg	Atorvastatin 10 mg once daily for 6 weeks
EZ/Simva 10 mg/20 mg	Ezetimibe (+) simvastatin combination tablet at doses of 10/20 mg
Atorva 20mg	Atorvastatin 20 mg once daily for 6 weeks
EZ/Simva 10 mg/40 mg	Ezetimibe (+) simvastatin combination tablet at doses of 10/40 mg
Atorva 40 mg	Atorvastatin 40 mg once daily for 6 weeks

Measured Values

	Atorva 10 mg	**EZ/Simva 10 mg/20 mg**	**Atorva 20mg**	**EZ/Simva 10 mg/40 mg**	**Atorva 40 mg**
Number of Participants Analyzed [units: participants]	**215**	**220**	**216**	**217**	**218**
Percent Change From Baseline in Triglyceride (TG) (mg/dL) at Week 6 [units: Percent Change] Median (95% Confidence Interval)	**-21.7 (-25.0 to -17.9)**	**-23.3 (-26.9 to -18.2)**	**-27.5 (-30.8 to -22.4)**	**-29.5 (-32.5 to -25.0)**	**-30.0 (-34.2 to -26.5)**

Statistical Analysis 1 for Percent Change From Baseline in Triglyceride (TG) (mg/dL) at Week 6

Groups [1]	Atorva 10 mg vs. EZ/Simva 10 mg/20 mg
Method [2]	Non-parametric ANOVA
P Value [3]	0.690
Mean Difference (Final Values) [4]	-0.9
95% Confidence Interval	-5.4 to 3.3

[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 using normal scores (Tukey method) based on ranks with terms for treatment and baseline risk stratum
[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 Percent Change From Baseline in Triglyceride (TG) (mg/dL) at Week 6

Groups [1]	EZ/Simva 10 mg/20 mg vs. Atorva 20mg
Method [2]	Non-parametric ANOVA
P Value [3]	0.200
Median Difference (Final Values) [4]	2.8
95% Confidence Interval	-1.6 to 7.1

[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 using normal scores (Tukey method) based on ranks with terms for treatment and baseline risk stratum
[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 3 for Percent Change From Baseline in Triglyceride (TG) (mg/dL) at Week 6

Groups [1]	EZ/Simva 10 mg/40 mg vs. Atorva 40 mg
Method [2]	Non-parametric ANOVA
P Value [3]	0.480
Median Difference (Final Values) [4]	-0.4
95% Confidence Interval	-4.7 to 3.9

[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 using normal scores (Tukey method) based on ranks with terms for treatment and baseline risk stratum
[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. Secondary: Percent Change From Baseline in High Density Lipoprotein Cholesterol (HDL-C) at Week 6 [Time Frame: Baseline and 6 Weeks]

Measure Type	Secondary
Measure Title	Percent Change From Baseline in High Density Lipoprotein Cholesterol (HDL-C) at Week 6
Measure Description	No text entered.
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 patients who took at least 1 dose of study medication and had a baseline (BL) value and at least one post BL value. Post BL measurements up to 3 days following the last dose of double-blind study medication were included in the analysis.

Reporting Groups

	Description
Atorva 10 mg	Atorvastatin 10 mg once daily for 6 weeks
EZ/Simva 10 mg/20 mg	Ezetimibe (+) simvastatin combination tablet at doses of 10/20 mg
Atorva 20mg	Atorvastatin 20 mg once daily for 6 weeks
EZ/Simva 10 mg/40 mg	Ezetimibe (+) simvastatin combination tablet at doses of 10/40 mg
Atorva 40 mg	Atorvastatin 40 mg once daily for 6 weeks

Measured Values

	Atorva 10 mg	**EZ/Simva 10 mg/20 mg**	**Atorva 20mg**	**EZ/Simva 10 mg/40 mg**	**Atorva 40 mg**
Number of Participants Analyzed [units: participants]	**215**	**219**	**216**	**217**	**217**
Percent Change From Baseline in High Density Lipoprotein Cholesterol (HDL-C) at Week 6 [units: Percent Change] Least Squares Mean (95% Confidence Interval)	**3.4 (1.5 to 5.3)**	**6.8 (4.9 to 8.7)**	**5.6 (3.7 to 7.5)**	**8.8 (6.9 to 10.7)**	**4.9 (3.0 to 6.8)**

Statistical Analysis 1 for Percent Change From Baseline in High Density Lipoprotein Cholesterol (HDL-C) at Week 6

Groups [1]	Atorva 10 mg vs. EZ/Simva 10 mg/20 mg
Method [2]	ANOVA

P Value [3]	0.013
Mean Difference (Final Values) [4]	3.4
Standard Error of the mean	(1.3)
95% Confidence Interval	0.7 to 6.0

[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:
	ANOVA with terms for treatment and baseline risk stratum
[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 Percent Change From Baseline in High Density Lipoprotein Cholesterol (HDL-C) at Week 6

Groups [1]	EZ/Simva 10 mg/20 mg vs. Atorva 20mg
Method [2]	ANOVA
P Value [3]	0.378
Mean Difference (Final Values) [4]	1.2
Standard Error of the mean	(1.3)
95% Confidence Interval	-1.5 to 3.8

[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:
	ANOVA with terms for treatment and baseline risk stratum
[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 3 for Percent Change From Baseline in High Density Lipoprotein Cholesterol (HDL-C) at Week 6

Groups [1]	EZ/Simva 10 mg/40 mg vs. Atorva 40 mg
Method [2]	ANOVA
P Value [3]	0.003
Mean Difference (Final Values) [4]	4.0
Standard Error of the mean	(1.3)

95% Confidence Interval	1.3 to 6.6

[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 with terms for treatment and baseline risk stratum
[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.

5. Secondary: Percent Change From Baseline in Non- High Density Lipoprotein Cholesterol (Non-HDL-C) at Week 6 [Time Frame: Baseline and 6 Weeks]

Measure Type	Secondary
Measure Title	Percent Change From Baseline in Non- High Density Lipoprotein Cholesterol (Non-HDL-C) at Week 6
Measure Description	No text entered.
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 patients who took at least 1 dose of study medication and had a baseline (BL) value and at least one post BL value. Post BL measurements up to 3 days following the last dose of double-blind study medication were included in the analysis.

Reporting Groups

	Description
Atorva 10 mg	Atorvastatin 10 mg once daily for 6 weeks
EZ/Simva 10 mg/20 mg	Ezetimibe (+) simvastatin combination tablet at doses of 10/20 mg
Atorva 20mg	Atorvastatin 20 mg once daily for 6 weeks
EZ/Simva 10 mg/40 mg	Ezetimibe (+) simvastatin combination tablet at doses of 10/40 mg
Atorva 40 mg	Atorvastatin 40 mg once daily for 6 weeks

Measured Values

	Atorva 10 mg	**EZ/Simva 10 mg/20 mg**	**Atorva 20mg**	**EZ/Simva 10 mg/40 mg**	**Atorva 40 mg**
Number of Participants Analyzed [units: participants]	**215**	**219**	**216**	**217**	**217**

Percent Change From Baseline in Non- High Density Lipoprotein Cholesterol (Non-HDL-C) at Week 6 [units: Percent Change] Least Squares Mean (95% Confidence Interval)	**-33.5 (-35.6 to -31.3)**	**-43.8 (-45.9 to -41.7)**	**-36.5 (-38.6 to -34.4)**	**-48.3 (-50.5 to -46.2)**	**-41.4 (-43.6 to -39.3)**

Statistical Analysis 1 for Percent Change From Baseline in Non- High Density Lipoprotein Cholesterol (Non-HDL-C) at Week 6

Groups [1]	Atorva 10 mg vs. EZ/Simva 10 mg/20 mg
Method [2]	ANOVA
P Value [3]	<0.001
Mean Difference (Final Values) [4]	-10.3
Standard Error of the mean	(1.5)
95% Confidence Interval	-13.3 to -7.3

[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 with terms for treatment and baseline risk stratum
[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 Percent Change From Baseline in Non- High Density Lipoprotein Cholesterol (Non-HDL-C) at Week 6

Groups [1]	EZ/Simva 10 mg/20 mg vs. Atorva 20mg
Method [2]	ANOVA
P Value [3]	<0.001
Mean Difference (Final Values) [4]	-7.3
Standard Error of the mean	(1.5)
95% Confidence Interval	-10.2 to -4.3

[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 with terms for treatment and baseline risk stratum
[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 3 for Percent Change From Baseline in Non- High Density Lipoprotein Cholesterol (Non-HDL-C) at Week 6

Groups [1]	EZ/Simva 10 mg/40 mg vs. Atorva 40 mg
Method [2]	ANOVA
P Value [3]	<0.001
Mean Difference (Final Values) [4]	-6.9
Standard Error of the mean	(1.5)
95% Confidence Interval	-9.9 to -3.9

[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 with terms for treatment and baseline risk stratum
[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. Secondary: Percent Change From Baseline in Very Low Density Lipoprotein Cholesterol (VLDL-C) at Week 6 [Time Frame: Baseline and 6 Weeks]

Measure Type	Secondary
Measure Title	Percent Change From Baseline in Very Low Density Lipoprotein Cholesterol (VLDL-C) at Week 6
Measure Description	No text entered.
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 patients who took at least 1 dose of study medication and had a baseline (BL) value and at least one post BL value. Post BL measurements up to 3 days following the last dose of double-blind study medication were included in the analysis.

Reporting Groups

	Description
Atorva 10 mg	Atorvastatin 10 mg once daily for 6 weeks
EZ/Simva 10 mg/20 mg	Ezetimibe (+) simvastatin combination tablet at doses of 10/20 mg
Atorva 20mg	Atorvastatin 20 mg once daily for 6 weeks

EZ/Simva 10 mg/40 mg	Ezetimibe (+) simvastatin combination tablet at doses of 10/40 mg
Atorva 40 mg	Atorvastatin 40 mg once daily for 6 weeks

Measured Values

	Atorva 10 mg	EZ/Simva 10 mg/20 mg	Atorva 20mg	EZ/Simva 10 mg/40 mg	Atorva 40 mg
Number of Participants Analyzed [units: participants]	**215**	**217**	**209**	**214**	**216**
Percent Change From Baseline in Very Low Density Lipoprotein Cholesterol (VLDL-C) at Week 6 [units: Percent Change] Least Squares Mean (95% Confidence Interval)	**-17.7 (-21.4 to -14.0)**	**-18.3 (-22.0 to -14.7)**	**-21.6 (-25.3 to -17.8)**	**-23.4 (-27.1 to -19.7)**	**-22.7 (-26.4 to -19.0)**

Statistical Analysis 1 for Percent Change From Baseline in Very Low Density Lipoprotein Cholesterol (VLDL-C) at Week 6

Groups [1]	Atorva 10 mg vs. EZ/Simva 10 mg/20 mg
Method [2]	ANOVA
P Value [3]	0.809
Mean Difference (Final Values) [4]	-0.6
Standard Error of the mean	(2.6)
95% Confidence Interval	-5.7 to 4.5

[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:
	ANOVA with terms for treatment and baseline risk stratum
[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 Percent Change From Baseline in Very Low Density Lipoprotein Cholesterol (VLDL-C) at Week 6

Groups [1]	EZ/Simva 10 mg/20 mg vs. Atorva 20mg
Method [2]	ANOVA
P Value [3]	0.217
Mean Difference (Final Values) [4]	3.2
Standard Error of the mean	(2.6)
95% Confidence Interval	-1.9 to 8.4

[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 with terms for treatment and baseline risk stratum
[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 3 for Percent Change From Baseline in Very Low Density Lipoprotein Cholesterol (VLDL-C) at Week 6

Groups [1]	EZ/Simva 10 mg/40 mg vs. Atorva 40 mg
Method [2]	ANOVA
P Value [3]	0.796
Mean Difference (Final Values) [4]	-0.7
Standard Error of the mean	(2.6)
95% Confidence Interval	-5.8 to 4.4

[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 with terms for treatment and baseline risk stratum
[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. Secondary: Percent Change From Baseline in Apolipoprotein- B (Apo-B) at Week 6 [Time Frame: Baseline and 6 Weeks]

Measure Type	Secondary
Measure Title	Percent Change From Baseline in Apolipoprotein- B (Apo-B) at Week 6
Measure Description	No text entered.
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 patients who took at least 1 dose of study medication and had a baseline (BL) value and at least one post BL value. Post BL measurements up to 3 days following the last dose of double-blind study medication were

included in the analysis.

Reporting Groups

	Description
Atorva 10 mg	Atorvastatin 10 mg once daily for 6 weeks
EZ/Simva 10 mg/20 mg	Ezetimibe (+) simvastatin combination tablet at doses of 10/20 mg
Atorva 20mg	Atorvastatin 20 mg once daily for 6 weeks
EZ/Simva 10 mg/40 mg	Ezetimibe (+) simvastatin combination tablet at doses of 10/40 mg
Atorva 40 mg	Atorvastatin 40 mg once daily for 6 weeks

Measured Values

	Atorva 10 mg	EZ/Simva 10 mg/20 mg	Atorva 20mg	EZ/Simva 10 mg/40 mg	Atorva 40 mg
Number of Participants Analyzed [units: participants]	**211**	**218**	**213**	**214**	**216**
Percent Change From Baseline in Apolipoprotein- B (Apo-B) at Week 6 [units: Percent Change] Least Squares Mean (95% Confidence Interval)	**-27.9 (-29.9 to -25.9)**	**-37.2 (-39.2 to -35.3)**	**-31.9 (-33.9 to -29.9)**	**-41.1 (-43.1 to -39.1)**	**-35.8 (-37.8 to -33.8)**

Statistical Analysis 1 for Percent Change From Baseline in Apolipoprotein- B (Apo-B) at Week 6

Groups [1]	Atorva 10 mg vs. EZ/Simva 10 mg/20 mg
Method [2]	ANOVA
P Value [3]	<0.001
Mean Difference (Final Values) [4]	-9.4
Standard Error of the mean	(1.4)
95% Confidence Interval	-12.1 to -6.6

[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 with terms for treatment and baseline risk stratum
[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 Percent Change From Baseline in Apolipoprotein- B (Apo-B) at Week 6

Groups [1]	EZ/Simva 10 mg/20 mg vs. Atorva 20mg

Method [2]	ANOVA
P Value [3]	<0.001
Mean Difference (Final Values) [4]	-5.3
Standard Error of the mean	(1.4)
95% Confidence Interval	-8.1 to -2.6

[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 with terms for treatment and baseline risk stratum
[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 3 for Percent Change From Baseline in Apolipoprotein- B (Apo-B) at Week 6

Groups [1]	EZ/Simva 10 mg/40 mg vs. Atorva 40 mg
Method [2]	ANOVA
P Value [3]	<0.001
Mean Difference (Final Values) [4]	-5.3
Standard Error of the mean	(1.4)
95% Confidence Interval	-8.0 to -2.5

[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:
	ANOVA with terms for treatment and baseline risk stratum
[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. Secondary: Percent Change From Baseline in Apolipoprotein-A1 (Apo-A1) at Week 6 [Time Frame: Baseline and 6 Weeks]

Measure Type	Secondary
Measure Title	Percent Change From Baseline in Apolipoprotein-A1 (Apo-A1) at Week 6

Measure Description	No text entered.
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 patients who took at least 1 dose of study medication and had a baseline (BL) value and at least one post BL value. Post BL measurements up to 3 days following the last dose of double-blind study medication were included in the analysis.

Reporting Groups

	Description
Atorva 10 mg	Atorvastatin 10 mg once daily for 6 weeks
EZ/Simva 10 mg/20 mg	Ezetimibe (+) simvastatin combination tablet at doses of 10/20 mg
Atorva 20mg	Atorvastatin 20 mg once daily for 6 weeks
EZ/Simva 10 mg/40 mg	Ezetimibe (+) simvastatin combination tablet at doses of 10/40 mg
Atorva 40 mg	Atorvastatin 40 mg once daily for 6 weeks

Measured Values

	Atorva 10 mg	**EZ/Simva 10 mg/20 mg**	**Atorva 20mg**	**EZ/Simva 10 mg/40 mg**	**Atorva 40 mg**
Number of Participants Analyzed [units: participants]	**211**	**219**	**213**	**214**	**216**
Percent Change From Baseline in Apolipoprotein-A1 (Apo-A1) at Week 6 [units: Percent Change] Least Squares Mean (95% Confidence Interval)	**0.8 (-1.0 to 2.5)**	**3.2 (1.5 to 4.9)**	**1.0 (-0.7 to 2.7)**	**3.0 (1.3 to 4.7)**	**1.4 (-0.3 to 3.1)**

Statistical Analysis 1 for Percent Change From Baseline in Apolipoprotein-A1 (Apo-A1) at Week 6

Groups [1]	Atorva 10 mg vs. EZ/Simva 10 mg/20 mg
Method [2]	ANOVA
P Value [3]	0.042
Mean Difference (Final Values) [4]	2.4
Standard Error of the mean	(1.2)
95% Confidence Interval	0.1 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:
	ANOVA with terms for treatment and baseline risk stratum

[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 Percent Change From Baseline in Apolipoprotein-A1 (Apo-A1) at Week 6

Groups [1]	EZ/Simva 10 mg/20 mg vs. Atorva 20mg
Method [2]	ANOVA
P Value [3]	<0.001
Mean Difference (Final Values) [4]	2.2
Standard Error of the mean	(1.2)
95% Confidence Interval	-0.2 to 4.5

[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:
	ANOVA with terms for treatment and baseline risk stratum
[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 3 for Percent Change From Baseline in Apolipoprotein-A1 (Apo-A1) at Week 6

Groups [1]	EZ/Simva 10 mg/40 mg vs. Atorva 40 mg
Method [2]	ANOVA
P Value [3]	<0.001
Mean Difference (Final Values) [4]	1.6
Standard Error of the mean	(1.2)
95% Confidence Interval	-7.0 to 4.0

[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:
	ANOVA with terms for treatment and baseline risk stratum
[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. Secondary: Percent Change From Baseline in Total-Cholesterol: High Density Lipoprotein-Cholesterol (Total-C:HDL- C) at Week 6 [Time Frame: Baseline and 6 Weeks]

Measure Type	Secondary
Measure Title	Percent Change From Baseline in Total-Cholesterol: High Density Lipoprotein-Cholesterol (Total-C:HDL- C) at Week 6
Measure Description	No text entered.
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 patients who took at least 1 dose of study medication and had a baseline (BL) value and at least one post BL value. Post BL measurements up to 3 days following the last dose of double-blind study medication were included in the analysis.

Reporting Groups

	Description
Atorva 10 mg	Atorvastatin 10 mg once daily for 6 weeks
EZ/Simva 10 mg/20 mg	Ezetimibe (+) simvastatin combination tablet at doses of 10/20 mg
Atorva 20mg	Atorvastatin 20 mg once daily for 6 weeks
EZ/Simva 10 mg/40 mg	Ezetimibe (+) simvastatin combination tablet at doses of 10/40 mg
Atorva 40 mg	Atorvastatin 40 mg once daily for 6 weeks

Measured Values

	Atorva 10 mg	**EZ/Simva 10 mg/20 mg**	**Atorva 20mg**	**EZ/Simva 10 mg/40 mg**	**Atorva 40 mg**
Number of Participants Analyzed [units: participants]	**215**	**219**	**216**	**217**	**217**
Percent Change From Baseline in Total-Cholesterol: High Density Lipoprotein-Cholesterol (Total-C:HDL- C) at Week 6 [units: Percent Change] Least Squares Mean (95% Confidence Interval)	**-28.1 (-30.1 to -26.0)**	**-36.9 (-38.9 to -34.8)**	**-31.5 (-33.6 to -29.5)**	**-41.2 (-43.2 to -39.1)**	**-35.3 (-37.3 to -33.2)**

Statistical Analysis 1 for Percent Change From Baseline in Total-Cholesterol: High Density Lipoprotein-Cholesterol (Total-C:HDL- C) at Week 6

Groups [1]	Atorva 10 mg vs. EZ/Simva 10 mg/20 mg
Method [2]	ANOVA

P Value [3]	<0.001
Mean Difference (Final Values) [4]	-8.8
Standard Error of the mean	(1.4)
95% Confidence Interval	-11.6 to -6.0

[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:
	ANOVA with terms for treatment and baseline risk stratum
[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 Percent Change From Baseline in Total-Cholesterol: High Density Lipoprotein-Cholesterol (Total-C:HDL- C) at Week 6

Groups [1]	EZ/Simva 10 mg/20 mg vs. Atorva 20mg
Method [2]	ANOVA
P Value [3]	<0.001
Mean Difference (Final Values) [4]	-5.3
Standard Error of the mean	(1.4)
95% Confidence Interval	-8.2 to -2.5

[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:
	ANOVA with terms for treatment and baseline risk stratum
[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 3 for Percent Change From Baseline in Total-Cholesterol: High Density Lipoprotein-Cholesterol (Total-C:HDL- C) at Week 6

Groups [1]	EZ/Simva 10 mg/40 mg vs. Atorva 40 mg
Method [2]	ANOVA
P Value [3]	<0.001
Mean Difference (Final Values) [4]	-5.9
Standard Error of the mean	(1.4)

95% Confidence Interval	-8.7 to -3.1

[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 with terms for treatment and baseline risk stratum
[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. Secondary: Percent Change From Baseline in Low Density Lipoprotein Cholesterol: High Density Lipoprotein Cholesterol (LDL-C: HDL-C) at Week 6 [Time Frame: Baseline and 6 Weeks]

Measure Type	Secondary
Measure Title	Percent Change From Baseline in Low Density Lipoprotein Cholesterol: High Density Lipoprotein Cholesterol (LDL-C: HDL-C) at Week 6
Measure Description	No text entered.
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 patients who took at least 1 dose of study medication and had a baseline (BL) value and at least one post BL value. Post BL measurements up to 3 days following the last dose of double-blind study medication were included in the analysis.

Reporting Groups

	Description
Atorva 10 mg	Atorvastatin 10 mg once daily for 6 weeks
EZ/Simva 10 mg/20 mg	Ezetimibe (+) simvastatin combination tablet at doses of 10/20 mg
Atorva 20mg	Atorvastatin 20 mg once daily for 6 weeks
EZ/Simva 10 mg/40 mg	Ezetimibe (+) simvastatin combination tablet at doses of 10/40 mg
Atorva 40 mg	Atorvastatin 40 mg once daily for 6 weeks

Measured Values

	Atorva 10 mg	EZ/Simva 10 mg/20 mg	Atorva 20mg	EZ/Simva 10 mg/40 mg	Atorva 40 mg
Number of Participants Analyzed	**215**	**219**	**215**	**217**	**217**

[units: participants]					
Percent Change From Baseline in Low Density Lipoprotein Cholesterol: High Density Lipoprotein Cholesterol (LDL-C: HDL-C) at Week 6 [units: Percent Change] Least Squares Mean (95% Confidence Interval)	**-37.8 (-40.3 to -35.2)**	**-51.8 (-54.3 to -49.3)**	**-42.1 (-44.7 to -39.6)**	**-56.6 (-59.2 to -54.1)**	**-48.2 (-50.7 to -45.6)**

Statistical Analysis 1 for Percent Change From Baseline in Low Density Lipoprotein Cholesterol: High Density Lipoprotein Cholesterol (LDL-C: HDL-C) at Week 6

Groups [1]	Atorva 10 mg vs. EZ/Simva 10 mg/20 mg
Method [2]	ANOVA
P Value [3]	<0.001
Mean Difference (Final Values) [4]	-14.0
Standard Error of the mean	(1.8)
95% Confidence Interval	-17.6 to -10.5

[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:
	ANOVA with terms for treatment and baseline risk stratum
[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 Percent Change From Baseline in Low Density Lipoprotein Cholesterol: High Density Lipoprotein Cholesterol (LDL-C: HDL-C) at Week 6

Groups [1]	EZ/Simva 10 mg/20 mg vs. Atorva 20mg
Method [2]	ANOVA
P Value [3]	<0.001
Mean Difference (Final Values) [4]	-9.7
Standard Error of the mean	(1.8)
95% Confidence Interval	-13.2 to -6.1

[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 with terms for treatment and baseline risk stratum
[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 3 for Percent Change From Baseline in Low Density Lipoprotein Cholesterol: High Density Lipoprotein Cholesterol (LDL-C: HDL-C) at Week 6

Groups [1]	EZ/Simva 10 mg/40 mg vs. Atorva 40 mg
Method [2]	ANOVA
P Value [3]	<0.001
Mean Difference (Final Values) [4]	-8.5
Standard Error of the mean	(1.8)
95% Confidence Interval	-12.0 to -4.9

[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 with terms for treatment and baseline risk stratum
[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.

11. Secondary: Percent Change From Baseline in Apolipoprotein-B: Apolipoprotein-A1 (Apo-B:Apo-A1) at Week 6 [Time Frame: Baseline and 6 weeks]

Measure Type	Secondary
Measure Title	Percent Change From Baseline in Apolipoprotein-B: Apolipoprotein-A1 (Apo-B:Apo-A1) at Week 6
Measure Description	No text entered.
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 patients who took at least 1 dose of study medication and had a baseline (BL) value and at least one post BL value. Post BL measurements up to 3 days following the last dose of double-blind study medication were included in the analysis.

Reporting Groups

	Description

Atorva 10 mg	Atorvastatin 10 mg once daily for 6 weeks
EZ/Simva 10 mg/20 mg	Ezetimibe (+) simvastatin combination tablet at doses of 10/20 mg
Atorva 20mg	Atorvastatin 20 mg once daily for 6 weeks
EZ/Simva 10 mg/40 mg	Ezetimibe (+) simvastatin combination tablet at doses of 10/40 mg
Atorva 40 mg	Atorvastatin 40 mg once daily for 6 weeks

Measured Values

	Atorva 10 mg	EZ/Simva 10 mg/20 mg	Atorva 20mg	EZ/Simva 10 mg/40 mg	Atorva 40 mg
Number of Participants Analyzed [units: participants]	**211**	**218**	**213**	**214**	**216**
Percent Change From Baseline in Apolipoprotein-B: Apolipoprotein-A1 (Apo-B:Apo-A1) at Week 6 [units: Percent Change] Least Squares Mean (95% Confidence Interval)	**-27.4 (-29.6 to -25.2)**	**-38.4 (-40.6 to -36.2)**	**-32.0 (-34.2 to -29.8)**	**-41.9 (-44.1 to -39.7)**	**-36.2 (-38.4 to -34.0)**

Statistical Analysis 1 for Percent Change From Baseline in Apolipoprotein-B: Apolipoprotein-A1 (Apo-B:Apo-A1) at Week 6

Groups [1]	Atorva 10 mg vs. EZ/Simva 10 mg/20 mg
Method [2]	ANOVA
P Value [3]	<0.001
Mean Difference (Final Values) [4]	-11.0
Standard Error of the mean	(1.5)
95% Confidence Interval	-14.0 to -8.0

[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:
	ANOVA with terms for treatment and baseline risk stratum
[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 Percent Change From Baseline in Apolipoprotein-B: Apolipoprotein-A1 (Apo-B:Apo-A1) at Week 6

Groups [1]	EZ/Simva 10 mg/20 mg vs. Atorva 20mg
Method [2]	ANOVA
P Value [3]	<0.001
Mean Difference (Final Values) [4]	-6.4

Standard Error of the mean	(1.5)
95% Confidence Interval	-9.4 to -3.3

[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 with terms for treatment and baseline risk stratum
[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 3 for Percent Change From Baseline in Apolipoprotein-B: Apolipoprotein-A1 (Apo-B:Apo-A1) at Week 6

Groups [1]	EZ/Simva 10 mg/40 mg vs. Atorva 40 mg
Method [2]	ANOVA
P Value [3]	<0.001
Mean Difference (Final Values) [4]	-5.7
Standard Error of the mean	(1.5)
95% Confidence Interval	-8.7 to -2.7

[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 with terms for treatment and baseline risk stratum
[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.

12. Secondary: Percent Change From Baseline in Non-High Density Lipoprotein Cholesterol: High Density Lipoprotein Cholesterol (Non-HDL-C:HDL-C) at Week 6 [Time Frame: Baseline and 6 Weeks]

Measure Type	Secondary
Measure Title	Percent Change From Baseline in Non-High Density Lipoprotein Cholesterol: High Density Lipoprotein Cholesterol (Non-HDL-C:HDL-C) at Week 6
Measure Description	No text entered.
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 patients who took at least 1 dose of study medication and had a baseline (BL) value and at least one post BL value. Post BL measurements up to 3 days following the last dose of double-blind study medication were included in the analysis.

Reporting Groups

	Description
Atorva 10 mg	Atorvastatin 10 mg once daily for 6 weeks
EZ/Simva 10 mg/20 mg	Ezetimibe (+) simvastatin combination tablet at doses of 10/20 mg
Atorva 20mg	Atorvastatin 20 mg once daily for 6 weeks
EZ/Simva 10 mg/40 mg	Ezetimibe (+) simvastatin combination tablet at doses of 10/40 mg
Atorva 40 mg	Atorvastatin 40 mg once daily for 6 weeks

Measured Values

	Atorva 10 mg	**EZ/Simva 10 mg/20 mg**	**Atorva 20mg**	**EZ/Simva 10 mg/40 mg**	**Atorva 40 mg**
Number of Participants Analyzed [units: participants]	**215**	**219**	**216**	**217**	**217**
Percent Change From Baseline in Non-High Density Lipoprotein Cholesterol: High Density Lipoprotein Cholesterol (Non-HDL-C:HDL-C) at Week 6 [units: Percent Change] Least Squares Mean (95% Confidence Interval)	**-34.7 (-37.2 to -32.2)**	**-46.2 (-48.6 to -43.7)**	**-39.2 (-41.7 to -36.7)**	**-51.2 (-53.7 to -48.7)**	**-43.5 (-46.0 to -41.0)**

Statistical Analysis 1 for Percent Change From Baseline in Non-High Density Lipoprotein Cholesterol: High Density Lipoprotein Cholesterol (Non-HDL-C:HDL-C) at Week 6

Groups [1]	Atorva 10 mg vs. EZ/Simva 10 mg/20 mg
Method [2]	ANOVA
P Value [3]	<0.001
Mean Difference (Final Values) [4]	-11.5
Standard Error of the mean	(1.8)
95% Confidence Interval	-15.0 to -8.1

[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 with terms for treatment and baseline risk stratum
[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 Percent Change From Baseline in Non-High Density Lipoprotein Cholesterol: High Density Lipoprotein Cholesterol (Non-HDL-C:HDL-C) at Week 6

Groups [1]	EZ/Simva 10 mg/20 mg vs. Atorva 20mg
Method [2]	ANOVA
P Value [3]	<0.001
Mean Difference (Final Values) [4]	-7.0
Standard Error of the mean	(1.8)
95% Confidence Interval	-10.4 to -3.6

[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 with terms for treatment and baseline risk stratum
[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 3 for Percent Change From Baseline in Non-High Density Lipoprotein Cholesterol: High Density Lipoprotein Cholesterol (Non-HDL-C:HDL-C) at Week 6

Groups [1]	EZ/Simva 10 mg/40 mg vs. Atorva 40 mg
Method [2]	ANOVA
P Value [3]	<0.001
Mean Difference (Final Values) [4]	-7.7
Standard Error of the mean	(1.8)
95% Confidence Interval	-11.2 to -4.3

[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 with terms for treatment and baseline risk stratum
[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.

13. Secondary: Percent Change From Baseline in Low Density Lipoprotein Cholesterol (LDL-C) at Week 6 in Patients With Atherosclerotic Vascular Disease (AVD) [Time Frame: Baseline and 6 Weeks]

Measure Type	Secondary
Measure Title	Percent Change From Baseline in Low Density Lipoprotein Cholesterol (LDL-C) at Week 6 in Patients With Atherosclerotic Vascular Disease (AVD)
Measure Description	No text entered.
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 patients who took at least 1 dose of study medication and had a baseline (BL) value and at least one post BL value. Post BL measurements up to 3 days following the last dose of double-blind study medication were included in the analysis.

Reporting Groups

	Description
Atorva 10 mg	Atorvastatin 10 mg once daily for 6 weeks
EZ/Simva 10 mg/20 mg	Ezetimibe (+) simvastatin combination tablet at doses of 10/20 mg
Atorva 20mg	Atorvastatin 20 mg once daily for 6 weeks
EZ/Simva 10 mg/40 mg	Ezetimibe (+) simvastatin combination tablet at doses of 10/40 mg
Atorva 40 mg	Atorvastatin 40 mg once daily for 6 weeks

Measured Values

	Atorva 10 mg	**EZ/Simva 10 mg/20 mg**	**Atorva 20mg**	**EZ/Simva 10 mg/40 mg**	**Atorva 40 mg**
Number of Participants Analyzed [units: participants]	**64**	**71**	**59**	**61**	**63**
Percent Change From Baseline in Low Density Lipoprotein Cholesterol (LDL-C) at Week 6 in Patients With Atherosclerotic Vascular Disease (AVD) [units: Percent Change] Least Squares Mean (95% Confidence Interval)	**-37.1 (-41.4 to -32.7)**	**-48.7 (-52.8 to -44.6)**	**-36.9 (-41.5 to -32.4)**	**-56.1 (-60.6 to -51.7)**	**-45.8 (-50.2 to -41.5)**

No statistical analysis provided for Percent Change From Baseline in Low Density Lipoprotein Cholesterol (LDL-C) at Week 6 in Patients With Atherosclerotic Vascular Disease (AVD)

14. Secondary: Percent Change From Baseline in Low Density Lipoprotein Cholesterol (LDL-C) at Week 6 in Patients Without Atherosclerotic Vascular Disease (AVD) [Time Frame: Baseline and 6 Weeks]

Measure Type	Secondary
Measure Title	Percent Change From Baseline in Low Density Lipoprotein Cholesterol (LDL-C) at Week 6 in Patients Without Atherosclerotic Vascular Disease (AVD)
Measure Description	No text entered.
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 patients who took at least 1 dose of study medication and had a baseline (BL) value and at least one post BL value. Post BL measurements up to 3 days following the last dose of double-blind study medication were included in the analysis.

Reporting Groups

	Description
Atorva 10 mg	Atorvastatin 10 mg once daily for 6 weeks
EZ/Simva 10 mg/20 mg	Ezetimibe (+) simvastatin combination tablet at doses of 10/20 mg
Atorva 20mg	Atorvastatin 20 mg once daily for 6 weeks
EZ/Simva 10 mg/40 mg	Ezetimibe (+) simvastatin combination tablet at doses of 10/40 mg
Atorva 40 mg	Atorvastatin 40 mg once daily for 6 weeks

Measured Values

	Atorva 10 mg	**EZ/Simva 10 mg/20 mg**	**Atorva 20mg**	**EZ/Simva 10 mg/40 mg**	**Atorva 40 mg**
Number of Participants Analyzed [units: participants]	**151**	**148**	**156**	**156**	**154**
Percent Change From Baseline in Low Density Lipoprotein Cholesterol (LDL-C) at Week 6 in Patients Without Atherosclerotic Vascular Disease (AVD) [units: Percent Change] Least Squares Mean (95% Confidence Interval)	**-36.3 (-39.1 to -33.5)**	**-50.1 (-52.9 to -47.2)**	**-40.3 (-43.1 to -37.6)**	**-53.2 (-55.9 to -50.4)**	**-46.1 (-48.9 to -43.3)**

No statistical analysis provided for Percent Change From Baseline in Low Density Lipoprotein Cholesterol (LDL-C) at Week 6 in Patients Without Atherosclerotic Vascular Disease (AVD)

15. Secondary: Percent Change From Baseline in High-Sensitivity C-reactive (Hs-CRP) (mg/dL) at Week 6 [Time Frame: Baseline and 6 Weeks]

Measure Type	Secondary
Measure Title	Percent Change From Baseline in High-Sensitivity C-reactive (Hs-CRP) (mg/dL) at Week 6
Measure Description	No text entered.

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 patients who took at least 1 dose of study medication and had a baseline (BL) value and at least one post BL value. Post BL measurements up to 3 days following the last dose of double-blind study medication were included in the analysis.

Reporting Groups

	Description
Atorva 10 mg	Atorvastatin 10 mg once daily for 6 weeks
EZ/Simva 10 mg/20 mg	Ezetimibe (+) simvastatin combination tablet at doses of 10/20 mg
Atorva 20mg	Atorvastatin 20 mg once daily for 6 weeks
EZ/Simva 10 mg/40 mg	Ezetimibe (+) simvastatin combination tablet at doses of 10/40 mg
Atorva 40 mg	Atorvastatin 40 mg once daily for 6 weeks

Measured Values

	Atorva 10 mg	**EZ/Simva 10 mg/20 mg**	**Atorva 20mg**	**EZ/Simva 10 mg/40 mg**	**Atorva 40 mg**
Number of Participants Analyzed [units: participants]	**216**	**218**	**210**	**216**	**215**
Percent Change From Baseline in High-Sensitivity C-reactive (Hs-CRP) (mg/dL) at Week 6 [units: Percent Change] Median (95% Confidence Interval)	**-16.8 (-21.7 to -10.6)**	**-17.2 (-24.1 to -12.5)**	**-22.4 (-26.1 to -14.6)**	**-27.6 (-33.3 to -21.4)**	**-30.0 (-33.3 to -25.0)**

Statistical Analysis 1 for Percent Change From Baseline in High-Sensitivity C-reactive (Hs-CRP) (mg/dL) at Week 6

Groups [1]	Atorva 10 mg vs. EZ/Simva 10 mg/20 mg
Method [2]	Non-parametric ANOVA
P Value [3]	0.420
Median Difference (Final Values) [4]	-2.9
95% Confidence Interval	-11.0 to 5.0

[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:
	ANOVA using normal scores (Tukey method) based on ranks with terms for treatment and baseline risk stratum
[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 Percent Change From Baseline in High-Sensitivity C-reactive (Hs-CRP) (mg/dL) at Week 6

Groups [1]	EZ/Simva 10 mg/20 mg vs. Atorva 20mg
Method [2]	Non-parametric ANOVA
P Value [3]	0.555
Median Difference (Final Values) [4]	-0.9
95% Confidence Interval	-9.5 to 7.2

[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 using normal scores (Tukey method) based on ranks with terms for treatment and baseline risk stratum
[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 3 for Percent Change From Baseline in High-Sensitivity C-reactive (Hs-CRP) (mg/dL) at Week 6

Groups [1]	EZ/Simva 10 mg/40 mg vs. Atorva 40 mg
Method [2]	Non-parametric ANOVA
P Value [3]	0.410
Median Difference (Final Values) [4]	2.3
95% Confidence Interval	-5.1 to 9.6

[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 using normal scores (Tukey method) based on ranks with terms for treatment and baseline risk stratum
[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.

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	No text entered.
Additional Description	No text entered.

Reporting Groups

	Description
Atorva 10 mg	Atorvastatin 10 mg once daily for 6 weeks
EZ/Simva 10 mg/20 mg	Ezetimibe (+) simvastatin combination tablet at doses of 10/20 mg
Atorva 20mg	Atorvastatin 20 mg once daily for 6 weeks
EZ/Simva 10 mg/40 mg	Ezetimibe (+) simvastatin combination tablet at doses of 10/40 mg
Atorva 40 mg	Atorvastatin 40 mg once daily for 6 weeks

Serious Adverse Events

	Atorva 10 mg	EZ/Simva 10 mg/20 mg	Atorva 20mg	EZ/Simva 10 mg/40 mg	Atorva 40 mg
Total, serious adverse events					
# participants affected	**4**	**0**	**1**	**1**	**4**
Cardiac disorders					
Acute Myocardial Infarction *					
# participants affected / at risk	**1/228 (0.44%)**	**0/226 (0.00%)**	**0/226 (0.00%)**	**0/224 (0.00%)**	**0/224 (0.00%)**
Atrial Fibrillation *					
# participants affected / at risk	**1/228 (0.44%)**	**0/226 (0.00%)**	**0/226 (0.00%)**	**0/224 (0.00%)**	**0/224 (0.00%)**
Atrioventricular Block Second Degree *					
# participants affected / at risk	**0/228 (0.00%)**	**0/226 (0.00%)**	**0/226 (0.00%)**	**1/224 (0.45%)**	**0/224 (0.00%)**
Sick Sinus Syndrome *					
# participants affected / at risk	**0/228 (0.00%)**	**0/226 (0.00%)**	**1/226 (0.44%)**	**0/224 (0.00%)**	**0/224 (0.00%)**
Tachyarrhythmia *					
# participants affected / at risk	**0/228 (0.00%)**	**0/226 (0.00%)**	**0/226 (0.00%)**	**0/224 (0.00%)**	**1/224 (0.45%)**
Hepatobiliary disorders					
Cholestasis *					

# participants affected / at risk	**0/228 (0.00%)**	**0/226 (0.00%)**	**0/226 (0.00%)**	**0/224 (0.00%)**	**1/224 (0.45%)**
Infections and infestations					
Urinary Tract Infection *					
# participants affected / at risk	**0/228 (0.00%)**	**0/226 (0.00%)**	**1/226 (0.44%)**	**0/224 (0.00%)**	**0/224 (0.00%)**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
Prostate Cancer *					
# participants affected / at risk	**0/228 (0.00%)**	**0/226 (0.00%)**	**0/226 (0.00%)**	**0/224 (0.00%)**	**1/224 (0.45%)**
Nervous system disorders					
Cerebrovascular Accident *					
# participants affected / at risk	**0/228 (0.00%)**	**0/226 (0.00%)**	**0/226 (0.00%)**	**0/224 (0.00%)**	**1/224 (0.45%)**
Headache *					
# participants affected / at risk	**1/228 (0.44%)**	**0/226 (0.00%)**	**0/226 (0.00%)**	**0/224 (0.00%)**	**0/224 (0.00%)**
Ischaemic Cerebral Infarction *					
# participants affected / at risk	**1/228 (0.44%)**	**0/226 (0.00%)**	**0/226 (0.00%)**	**0/224 (0.00%)**	**0/224 (0.00%)**

* Events were collected by non-systematic assessment

Other Adverse Events

Hide Other Adverse Events

Time Frame	No text entered.
Additional Description	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	1%

Reporting Groups

	Description
Atorva 10 mg	Atorvastatin 10 mg once daily for 6 weeks
EZ/Simva 10 mg/20 mg	Ezetimibe (+) simvastatin combination tablet at doses of 10/20 mg
Atorva 20mg	Atorvastatin 20 mg once daily for 6 weeks

EZ/Simva 10 mg/40 mg	Ezetimibe (+) simvastatin combination tablet at doses of 10/40 mg
Atorva 40 mg	Atorvastatin 40 mg once daily for 6 weeks

Other Adverse Events

	Atorva 10 mg	EZ/Simva 10 mg/20 mg	Atorva 20mg	EZ/Simva 10 mg/40 mg	Atorva 40 mg
Total, other (not including serious) adverse events					
# participants affected	**21**	**14**	**22**	**13**	**13**
Gastrointestinal disorders					
Any Gastrointestinal Disorders *					
# participants affected / at risk	**7/228 (3.07%)**	**6/226 (2.65%)**	**7/226 (3.10%)**	**4/224 (1.79%)**	**2/224 (0.89%)**
Abdominal Tenderness *					
# participants affected / at risk	**1/228 (0.44%)**	**2/226 (0.88%)**	**3/226 (1.33%)**	**1/224 (0.45%)**	**0/224 (0.00%)**
Diarrhoea *					
# participants affected / at risk	**5/228 (2.19%)**	**1/226 (0.44%)**	**3/226 (1.33%)**	**1/224 (0.45%)**	**1/224 (0.45%)**
Nausea *					
# participants affected / at risk	**1/228 (0.44%)**	**3/226 (1.33%)**	**1/226 (0.44%)**	**2/224 (0.89%)**	**1/224 (0.45%)**
General disorders					
Any General Disorders And Administration Site Conditions *					
# participants affected / at risk	**2/228 (0.88%)**	**2/226 (0.88%)**	**2/226 (0.88%)**	**1/224 (0.45%)**	**0/224 (0.00%)**
Fatigue *					
# participants affected / at risk	**2/228 (0.88%)**	**2/226 (0.88%)**	**2/226 (0.88%)**	**1/224 (0.45%)**	**0/224 (0.00%)**
Infections and infestations					
Any Infections and Infestations *					
# participants affected / at risk	**1/228 (0.44%)**	**1/226 (0.44%)**	**2/226 (0.88%)**	**2/224 (0.89%)**	**1/224 (0.45%)**
Nasopharyngitis *					
# participants affected / at risk	**1/228 (0.44%)**	**1/226 (0.44%)**	**2/226 (0.88%)**	**2/224 (0.89%)**	**1/224 (0.45%)**
Musculoskeletal and connective tissue disorders					
Any Musculoskeletal And Connective Tissue *					

Disorders					
# participants affected / at risk	**8/228 (3.51%)**	**7/226 (3.10%)**	**9/226 (3.98%)**	**5/224 (2.23%)**	**7/224 (3.13%)**
Arthralgia *					
# participants affected / at risk	**3/228 (1.32%)**	**1/226 (0.44%)**	**1/226 (0.44%)**	**2/224 (0.89%)**	**1/224 (0.45%)**
Back Pain *					
# participants affected / at risk	**0/228 (0.00%)**	**2/226 (0.88%)**	**0/226 (0.00%)**	**3/224 (1.34%)**	**2/224 (0.89%)**
Muscle Spasms *					
# participants affected / at risk	**2/228 (0.88%)**	**2/226 (0.88%)**	**3/226 (1.33%)**	**0/224 (0.00%)**	**1/224 (0.45%)**
Myalgia *					
# participants affected / at risk	**3/228 (1.32%)**	**2/226 (0.88%)**	**3/226 (1.33%)**	**0/224 (0.00%)**	**3/224 (1.34%)**
Pain In Extremity *					
# participants affected / at risk	**3/228 (1.32%)**	**1/226 (0.44%)**	**2/226 (0.88%)**	**1/224 (0.45%)**	**1/224 (0.45%)**
Nervous system disorders					
Any Nervous System Disorders *					
# participants affected / at risk	**4/228 (1.75%)**	**2/226 (0.88%)**	**4/226 (1.77%)**	**3/224 (1.34%)**	**2/224 (0.89%)**
Dizziness *					
# participants affected / at risk	**0/228 (0.00%)**	**2/226 (0.88%)**	**0/226 (0.00%)**	**3/224 (1.34%)**	**0/224 (0.00%)**
Headache *					
# participants affected / at risk	**4/228 (1.75%)**	**0/226 (0.00%)**	**4/226 (1.77%)**	**0/224 (0.00%)**	**2/224 (0.89%)**
Vascular disorders					
Any Vascular Disorders *					
# participants affected / at risk	**2/228 (0.88%)**	**0/226 (0.00%)**	**0/226 (0.00%)**	**0/224 (0.00%)**	**2/224 (0.89%)**
Hypertension *					
# participants affected / at risk	**2/228 (0.88%)**	**0/226 (0.00%)**	**0/226 (0.00%)**	**0/224 (0.00%)**	**0/224 (0.00%)**

* 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
15 patients were randomized but not treated. Since these patients were not treated no Adverse Event Data was collected.

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:

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No publications provided by Merck Sharp & Dohme Corp.

Publications automatically indexed to this study:

Rosen JB, Ballantyne CM, Hsueh WA, Lin J, Shah AK, Lowe RS, Tershakovec AM. Influence of metabolic syndrome factors and insulin resistance on the efficacy of ezetimibe/simvastatin and atorvastatin in patients with metabolic syndrome and atherosclerotic coronary heart disease risk. Lipids Health Dis. 2015 Sep 4;14:103. doi: 10.1186/s12944-015-0075-5.

Robinson JG, Ballantyne CM, Hsueh W, Rosen J, Lin J, Shah A, Lowe RS, Hanson ME, Tershakovec AM. Achievement of specified low-density lipoprotein cholesterol, non-high-density lipoprotein cholesterol apolipoprotein B, and high-sensitivity C-reactive protein levels with ezetimibe/simvastatin or atorvastatin in metabolic syndrome patients with and without atherosclerotic vascular disease (from the VYMET study). J Clin Lipidol. 2011 Nov-Dec;5(6):474-82. doi: 10.1016/j.jacl.2011.06.004. Epub 2011 Jun 15.

Responsible Party:	Merck Sharp & Dohme Corp.
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Health Authority: United States: Food and Drug Administration

TO TOP

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