A Study of Ezetimibe Added On to Rosuvastatin Versus Up Titration of Rosuvastatin in Patients With Hypercholesterolemia (MK0653-139)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

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

ClinicalTrials.gov Identifier:
NCT00783263

First received: October 30, 2008
Last updated: January 19, 2015
Last verified: January 2015
History of Changes

Results First Received: August 10, 2011

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: Comparator: rosuvastatin 5 mg + ezetimibe 10 mg Drug: Comparator: rosuvastatin 10 mg Drug: Comparator: rosuvastatin 10 mg + ezetimibe 10 mg Drug: Comparator: rosuvastatin 20 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
No text entered.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
No text entered.

Reporting Groups

	Description

Rosuvastatin 5 mg + Ezetimibe 10 mg	Participants who received open label rosuvastatin 5 mg tablets once daily for 4 to 5 weeks then received 10 mg ezetimibe tablets once daily plus 5 mg rosuvastatin for an additional 6 weeks.
Rosuvastatin 10 mg	Participants who received open label rosuvastatin 5 mg tablets once daily for 4 to 5 weeks then received rosuvastatin 10 mg once daily for 6 additional weeks.
Rosuvastatin 10 mg + Ezetimibe 10 mg	Participants who received open label rosuvastatin 10 mg tablets once daily for 4 to 5 weeks then received 10 mg ezetimibe tablets once daily plus 10 mg rosuvastatin for an additional 6 weeks.
Rosuvastatin 20 mg	Participants who received open label rosuvastatin 10 mg tablets once daily for 4 to 5 weeks then received rosuvastatin 20 mg once daily for 6 additional weeks.

Participant Flow: Overall Study

	Rosuvastatin 5 mg + Ezetimibe 10 mg	Rosuvastatin 10 mg	Rosuvastatin 10 mg + Ezetimibe 10 mg	Rosuvastatin 20 mg
STARTED	99	98	122	121
COMPLETED	95	96	119	118
NOT COMPLETED	4	2	3	3
Adverse Event	3	0	2	1
Lost to Follow-up	1	1	0	0
Withdrawal by Subject	0	1	1	2

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
Rosuvastatin 5 mg + Ezetimibe 10 mg	Participants who received open label rosuvastatin 5 mg tablets once daily for 4 to 5 weeks then received 10 mg ezetimibe tablets once daily plus 5 mg rosuvastatin for an additional 6 weeks.
Rosuvastatin 10 mg	Participants who received open label rosuvastatin 5 mg tablets once daily for 4 to 5 weeks then received rosuvastatin 10 mg once daily for 6 additional weeks.
Rosuvastatin 10 mg + Ezetimibe 10 mg	Participants who received open label rosuvastatin 10 mg tablets once daily for 4 to 5 weeks then received 10 mg ezetimibe tablets once daily plus 10 mg rosuvastatin for an additional 6 weeks.
Rosuvastatin 20 mg	Participants who received open label rosuvastatin 10 mg tablets once daily for 4 to 5 weeks then received rosuvastatin 20 mg once daily for 6 additional weeks.
Total	Total of all reporting groups

Baseline Measures

	Rosuvastatin 5 mg + Ezetimibe 10 mg	Rosuvastatin 10 mg	Rosuvastatin 10 mg + Ezetimibe 10 mg	Rosuvastatin 20 mg	Total
Number of					**440**

Participants [units: participants]	**99**	**98**	**122**	**121**	
Age, Customized [units: participants]					
< 65 years	**63**	**62**	**71**	**71**	**267**
≥ 65 years	**36**	**36**	**51**	**50**	**173**
Gender [units: participants]					
Female	**35**	**40**	**56**	**37**	**168**
Male	**64**	**58**	**66**	**84**	**272**

Outcome Measures

Hide All Outcome Measures

1. Primary: Percent Change From Baseline in LDL-Cholesterol (mg/dL) After 6 Weeks of Treatment [Time Frame: Baseline to 6 weeks]

Measure Type	Primary
Measure Title	Percent Change From Baseline in LDL-Cholesterol (mg/dL) After 6 Weeks of Treatment
Measure Description	The percent change from baseline in LDL-C (mg/dL) after 6 weeks of treatment in participants who were administered ezetimibe 10 mg to rosuvastatin (5 or 10 mg) in comparison with doubling the baseline dose of rosuvastatin (10 or 20 mg) daily for 6 weeks.
Time Frame	Baseline to 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.
No text entered.

Reporting Groups

	Description
Rosuvastatin (5 or 10 mg) + Ezetimibe 10 mg	Participants who received open label rosuvastatin (5 or 10 mg) tablets once daily for 4 to 5 weeks then received 10 mg ezetimibe tablets once daily plus (5 or 10 mg) rosuvastatin for an additional 6 weeks.
Rosuvastatin (10 or 20 mg)	Participants who received open label rosuvastatin (5 or 10 mg) tablets once daily for 4 to 5 weeks then received rosuvastatin (10 or 20 mg) once daily for 6 additional weeks.

Measured Values

	Rosuvastatin (5 or 10 mg) + Ezetimibe 10 mg	**Rosuvastatin (10 or 20 mg)**
Number of Participants Analyzed [units: participants]	**219**	**217**

Percent Change From Baseline in LDL-Cholesterol (mg/dL) After 6 Weeks of Treatment [units: percent change] Mean (Standard Deviation)	-21.57 (25.09)	-5.58 (25.42)

Statistical Analysis 1 for Percent Change From Baseline in LDL-Cholesterol (mg/dL) After 6 Weeks of Treatment

Groups [1]	All groups
Method [2]	Longitudinal Data Analysis (LDA)
P Value [3]	<0.001
Mean Difference (Final Values) [4]	-15.25
95% Confidence Interval	-19.89 to -10.60

[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:
	Longitudinal Data Analysis was based on a constrained LDA model with terms for treatment, time, stratum and the interaction of time by treatment.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

2. Secondary: Percent Change From Baseline in LDL-Cholesterol (mg/dL) After 6 Weeks of Treatment in Each Stratum [Time Frame: Baseline to 6 weeks]

Measure Type	Secondary
Measure Title	Percent Change From Baseline in LDL-Cholesterol (mg/dL) After 6 Weeks of Treatment in Each Stratum
Measure Description	The percent change from baseline in LDL-C (mg/dL) after 6 weeks of treatment by stratum I and stratum II in participants who were administered with ezetimibe 10 mg to rosuvastatin (5 or 10 mg) in comparison with the doubling of the baseline dose of rosuvastatin (10 or 20 mg) daily for 6 weeks.
Time Frame	Baseline to 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.
No text entered.

Reporting Groups

	Description
Rosuvastatin 5 mg + Ezetimibe 10 mg (Stratum I)	Participants who received open label rosuvastatin 5 mg tablets once daily for 4 to 5 weeks

	then received 10 mg ezetimibe tablets once daily plus 5 mg rosuvastatin for an additional 6 weeks.
Rosuvastatin 10 mg (Stratum I)	Participants who received open label rosuvastatin 5 mg tablets once daily for 4 to 5 weeks then received rosuvastatin 10 mg once daily for 6 additional weeks.
Rosuvastatin 10 mg + Ezetimibe 10 mg (Stratum II)	Participants who received open label rosuvastatin 5 mg tablets once daily for 4 to 5 weeks then received rosuvastatin 10 mg once daily for 6 additional weeks.
Rosuvastatin 20 mg (Stratum II)	Participants who received open label rosuvastatin 10 mg tablets once daily for 4 to 5 weeks then received rosuvastatin 20 mg once daily for 6 additional weeks.

Measured Values

	Rosuvastatin 5 mg + Ezetimibe 10 mg (Stratum I)	Rosuvastatin 10 mg (Stratum I)	Rosuvastatin 10 mg + Ezetimibe 10 mg (Stratum II)	Rosuvastatin 20 mg (Stratum II)
Number of Participants Analyzed [units: participants]	**98**	**96**	**121**	**121**
Percent Change From Baseline in LDL-Cholesterol (mg/dL) After 6 Weeks of Treatment in Each Stratum [units: percentage change] Mean (Standard Deviation)	**-18.57 (26.35)**	**-4.96 (22.42)**	**-24.00 (23.86)**	**-6.07 (27.65)**

Statistical Analysis 1 for Percent Change From Baseline in LDL-Cholesterol (mg/dL) After 6 Weeks of Treatment in Each Stratum

Groups [1]	Rosuvastatin 5 mg + Ezetimibe 10 mg (Stratum I) vs. Rosuvastatin 10 mg (Stratum I)
Method [2]	Longitudinal Data Analysis (LDA)
P Value [3]	<0.001
Mean Difference (Final Values) [4]	-12.31
95% Confidence Interval	-18.95 to -5.67

[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:
	Longitudinal Data Analysis was based on a constrained LDA model with terms for treatment, time and the interaction of time by treatment.
[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 LDL-Cholesterol (mg/dL) After 6 Weeks of Treatment in Each Stratum

Groups [1]	Rosuvastatin 10 mg + Ezetimibe 10 mg (Stratum II) vs. Rosuvastatin 20 mg (Stratum II)
Method [2]	Longitudinal Data Analysis (LDA)
P Value [3]	<0.001

Mean Difference (Final Values) [4]	-17.46
95% Confidence Interval	-23.92 to -10.99

[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:
	Longitudinal Data Analysis was based on a constrained LDA model with terms for treatment, time and the interaction of time by treatment.
[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: Number of Participants Who Reached Their Target LDL-C Level [Time Frame: 6 weeks of treatment]

Measure Type	Secondary
Measure Title	Number of Participants Who Reached Their Target LDL-C Level
Measure Description	Participants were analyzed to evaluate the LDL-C (<100 mg/dL for moderately high risk patients and high risk patients without AVD and <70 mg/dL for high risk patients with AVD) lowering efficacy with the addition of ezetimibe 10 mg to (5 or 10 mg) compared with doubling the baseline rosuvastatin (10 or 20 mg), daily for 6 weeks of treatment.
Time Frame	6 weeks of treatment
Safety Issue	No

Population Description

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

Reporting Groups

	Description
Rosuvastatin (5 or 10 mg) + Ezetimibe 10 mg	Participants who received open label rosuvastatin 5 mg tablets once daily for 4 to 5 weeks then received 10 mg ezetimibe tablets once daily plus 5 mg rosuvastatin for an additional 6 weeks.
Rosuvastatin (10 or 20 mg)	Participants who received rosuvastatin (5 or 10 mg) mg tablets once daily for 4 to 5 weeks then received rosuvastatin (10 or 20 mg) once daily for 6 additional weeks.

Measured Values

	Rosuvastatin (5 or 10 mg) + Ezetimibe 10 mg	**Rosuvastatin (10 or 20 mg)**
Number of Participants Analyzed [units: participants]	**219**	**217**
Number of Participants Who Reached Their Target LDL-C Level [units: participants]	**130**	**67**

Statistical Analysis 1 for Number of Participants Who Reached Their Target LDL-C Level

Groups [1]	All groups
Method [2]	Logistic Regression
P Value [3]	<0.001
Odds Ratio (OR) [4]	4.5
95% Confidence Interval	2.9 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:
	Logistic Regression included terms for treatment, stratum and baseline LDL-C category (3 levels: <100, 100-<130, ≥130 mg/dL).
[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: Number of Participants in Each Stratum Who Reached Their Target LDL-C Level [Time Frame: 6 weeks of treatment]

Measure Type	Secondary
Measure Title	Number of Participants in Each Stratum Who Reached Their Target LDL-C Level
Measure Description	Participants in stratum I were analyzed to evaluate the LDL-C lowering efficacy with the additional of ezetimibe 10 mg to rosuvastatin 5 mg daily for 6 weeks compared with doubling the baseline dose to rosuvastatin 10 mg daily for 6 weeks. Participants in stratum II were analyzed to evaluate the LDL-C lowering efficacy with the additional of ezetimibe 10 mg to rosuvastatin 10 mg daily for 6 weeks compared with doubling the baseline dose to rosuvastatin 20 mg daily for 6 weeks.
Time Frame	6 weeks of treatment
Safety Issue	No

Population Description

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

Reporting Groups

	Description
Rosuvastatin 5 mg + Ezetimibe 10 mg (Stratum I)	Participants who received open label rosuvastatin 10 mg tablets once daily for 4 to 5 weeks then received 10 mg ezetimibe tablets once daily plus 10 mg rosuvastatin for an additional 6 weeks.
Rosuvastatin 10 mg (Stratum I)	Participants who received open label rosuvastatin 10 mg tablets once daily for 4 to 5 weeks then received rosuvastatin 20 mg once daily for 6 additional weeks.

Rosuvastatin 10 mg + Ezetimibe 10 mg (Stratum II)	Participants who received open label rosuvastatin 10 mg tablets once daily for 4 to 5 weeks then received 10 mg ezetimibe tablets once daily plus 10 mg rosuvastatin for an additional 6 weeks.
Rosuvastatin 20 mg (Stratum II)	Participants who received open label rosuvastatin 10 mg tablets once daily for 4 to 5 weeks then received rosuvastatin 20 mg once daily for 6 additional weeks.

Measured Values

	Rosuvastatin 5 mg + Ezetimibe 10 mg (Stratum I)	Rosuvastatin 10 mg (Stratum I)	Rosuvastatin 10 mg + Ezetimibe 10 mg (Stratum II)	Rosuvastatin 20 mg (Stratum II)
Number of Participants Analyzed [units: participants]	**98**	**96**	**121**	**121**
Number of Participants in Each Stratum Who Reached Their Target LDL-C Level [units: participants]	**54**	**30**	**76**	**37**

Statistical Analysis 1 for Number of Participants in Each Stratum Who Reached Their Target LDL-C Level

Groups [1]	Rosuvastatin 5 mg + Ezetimibe 10 mg (Stratum I) vs. Rosuvastatin 10 mg (Stratum I)
Method [2]	Logistic Regression
P Value [3]	<0.001
Odds Ratio (OR) [4]	3.1
95% Confidence Interval	1.7 to 5.8

[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:
	Logistic Regression included terms for treatment and baseline LDL-C category (3 levels: <100, 100-<130, >=130 mg/dL).
[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 Number of Participants in Each Stratum Who Reached Their Target LDL-C Level

Groups [1]	Rosuvastatin 10 mg + Ezetimibe 10 mg (Stratum II) vs. Rosuvastatin 20 mg (Stratum II)
Method [2]	Logistic Regression
P Value [3]	<0.001
Odds Ratio (OR) [4]	6.5
95% Confidence Interval	3.4 to 12.3

[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:
	Logistic Regression included terms for treatment and baseline LDL-C category (3 levels: <100, 100-<130, >=130 mg/dL).
[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: Number of Participants Who Reached the LDL-C Level of <70 mg/dl [Time Frame: 6 weeks of treatment]

Measure Type	Secondary
Measure Title	Number of Participants Who Reached the LDL-C Level of <70 mg/dl
Measure Description	Participants across all strata who reached the LDL-C Level of <70 mg/dl after the addition of ezetimibe 10 mg to rosuvastatin (5 or 10 mg) daily for 6 weeks compared with doubling the baseline dose of rosuvastatin (10 or 20 mg) daily for 6 weeks.
Time Frame	6 weeks of treatment
Safety Issue	No

Population Description

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

Reporting Groups

	Description
Rosuvastatin (5 or 10 mg) + Ezetimibe 10 mg	Participants who received open label rosuvastatin 5 or 10 mg tablets once daily for 4 to 5 weeks then received 10 or 20 mg ezetimibe tablets once daily plus 5 mg rosuvastatin for an additional 6 weeks.
Rosuvastatin 10 or 20 mg	Participants who received rosuvastatin (5 or 10 mg) tablets once daily for 4 to 5 weeks then received rosuvastatin (10 or 20 mg) once daily for 6 additional weeks.

Measured Values

	Rosuvastatin (5 or 10 mg) + Ezetimibe 10 mg	**Rosuvastatin 10 or 20 mg**
Number of Participants Analyzed [units: participants]	**219**	**217**
Number of Participants Who Reached the LDL-C Level of <70 mg/dl [units: participants]	**96**	**38**

Statistical Analysis 1 for Number of Participants Who Reached the LDL-C Level of <70 mg/dl

Groups [1]	All groups
[2]	

Method	Logistic Regression
P Value [3]	<0.001
Odds Ratio (OR) [4]	8.0
95% Confidence Interval	4.6 to 14.0

[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:
	No text entered.
[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: Number of Participants in Each Stratum Who Reached the LDL-C Level of <70 mg/dl [Time Frame: 6 weeks of treatment]

Measure Type	Secondary
Measure Title	Number of Participants in Each Stratum Who Reached the LDL-C Level of <70 mg/dl
Measure Description	Participants in stratum I and in stratum II who reached the LDL-C Level of <70 mg/dl after the addition of ezetimibe to rosuvastatin (5 or 10 mg)daily for 6 weeks compared with doubling the baseline dose of rosuvastatin (10 or 20 mg).
Time Frame	6 weeks of treatment
Safety Issue	No

Population Description

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

Reporting Groups

	Description
Rosuvastatin 5 mg + Ezetimibe 10 mg	Participants who received open label rosuvastatin 5 mg tablets once daily for 4 to 5 weeks then received 10 mg ezetimibe tablets once daily plus 5 mg rosuvastatin for an additional 6 weeks.
Rosuvastatin 10 mg	Participants who received open label rosuvastatin 5 mg tablets once daily for 4 to 5 weeks then received rosuvastatin 10 mg once daily for 6 additional weeks.
Rosuvastatin 10 mg + Ezetimibe 10 mg	Participants who received open label rosuvastatin 10 mg tablets once daily for 4 to 5 weeks then received 10 mg ezetimibe tablets once daily plus 10 mg rosuvastatin for an additional 6 weeks.
Rosuvastatin 20 mg	Participants who received open label rosuvastatin 10 mg tablets once daily for 4 to 5 weeks then received rosuvastatin 20 mg once daily for 6 additional weeks.

Measured Values

	Rosuvastatin 5 mg +	**Rosuvastatin**	**Rosuvastatin 10 mg +**	**Rosuvastatin**

	Ezetimibe 10 mg	10 mg	Ezetimibe 10 mg	20 mg
Number of Participants Analyzed [units: participants]	**98**	**96**	**121**	**121**
Number of Participants in Each Stratum Who Reached the LDL-C Level of <70 mg/dl [units: participants]	**31**	**12**	**65**	**26**

Statistical Analysis 1 for Number of Participants in Each Stratum Who Reached the LDL-C Level of <70 mg/dl

Groups [1]	Rosuvastatin 5 mg + Ezetimibe 10 mg vs. Rosuvastatin 10 mg
Method [2]	Logistic Regression
P Value [3]	<0.001
Odds Ratio (OR) [4]	5.1
95% Confidence Interval	2.2 to 11.8

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	Stratum I
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[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 Number of Participants in Each Stratum Who Reached the LDL-C Level of <70 mg/dl

Groups [1]	Rosuvastatin 10 mg + Ezetimibe 10 mg vs. Rosuvastatin 20 mg
Method [2]	Logistic Regression
P Value [3]	<0.001
Odds Ratio (OR) [4]	11.4
95% Confidence Interval	5.2 to 24.8

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	Stratum II
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[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 Other Lipid, Lipoprotein, Apolipoprotein and High-sensitivity C-reactive Protein (Hs-CRP)Levels [Time Frame: Baseline to 6 weeks]

Measure Type	Secondary
Measure Title	Percent Change From Baseline in Other Lipid, Lipoprotein, Apolipoprotein and High-sensitivity C-reactive Protein (Hs-CRP)Levels
Measure Description	Participants who were analyzed to assess the Total Cholesterol (TC), Triglycerides, High-Density Lipoprotein Cholesterol, Non High-Density Lipoprotein Cholesterol, LDL Cholesterol/HDL Cholesterol, Total Cholesterol/HDL Cholesterol, Non-HDL Cholesterol/HDL Cholesterol, Apolipoprotein B (Apo B), Apolipoprotein A-I (Apo A-I), Apolipoprotein B/Apo A-I, high-sensitivity C-reactive protein (hs-CRP)levels after 6 weeks of treatment.
Time Frame	Baseline to 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.
No text entered.

Reporting Groups

	Description
Rosuvastatin (5 or 10 mg) + Ezetimibe 10 mg	Participants who received open label rosuvastatin 5 or 10 mg tablets once daily for 4 to 5 weeks then received 10 or 20 mg ezetimibe tablets once daily plus 5 mg rosuvastatin for an additional 6 weeks.
Rosuvastatin 10 or 20 mg	Participants who received rosuvastatin (5 or 10 mg) tablets once daily for 4 to 5 weeks then received rosuvastatin (10 or 20 mg) once daily for 6 additional weeks.

Measured Values

	Rosuvastatin (5 or 10 mg) + Ezetimibe 10 mg	**Rosuvastatin 10 or 20 mg**
Number of Participants Analyzed [units: participants]	**219**	**217**
Percent Change From Baseline in Other Lipid, Lipoprotein, Apolipoprotein and High-sensitivity C-reactive Protein (Hs-CRP)Levels [units: percentage change] Mean (Standard Deviation)		
Total Cholesterol (TC)	**-13.00 (17.51)**	**-3.76 (14.35)**
Triglycerides	**-5.96 (36.45)**	**-3.60 (32.83)**
High-Density Lipoprotein Cholesterol	**-0.67 (15.51)**	**2.18 (13.38)**
Non High-Density Liproprotein Cholesterol	**-17.59 (23.55)**	**-5.29 (21.20)**
LDL Cholesterol/HDL Cholesterol	**-19.48 (27.63)**	**-6.18 (27.82)**
Total Cholesterol/HDL Cholesterol	**-10.57 (25.87)**	**-4.40 (18.27)**
Non-HDL Cholestrol/HDL Cholesterol	**-14.51 (35.39)**	**-5.31 (26.63)**
Apolipoprotein B (Apo B)	**-14.31 (18.61)**	**-4.25 (17.56)**

Apolipoprotein A-I (Apo A-I)	**-1.44 (12.49)**	**1.06 (11.56)**
Apolipoprotein B/Apo A-I	**-11.98 (20.84)**	**-4.11 (19.61)**
hs-C-Reactive Protein	**-13.98 (72.19)**	**-12.82 (73.08)**

Statistical Analysis 1 for Percent Change From Baseline in Other Lipid, Lipoprotein, Apolipoprotein and High-sensitivity C-reactive Protein (Hs-CRP)Levels

Groups [1]	All groups
Method [2]	Longitudinal Data Analysis
P Value [3]	<0.001
Mean Difference (Final Values) [4]	-8.65
95% Confidence Interval	-11.59 to -5.71

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	Total Cholesterol (mg/dL)
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[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 Other Lipid, Lipoprotein, Apolipoprotein and High-sensitivity C-reactive Protein (Hs-CRP)Levels

Groups [1]	All groups
Method [2]	Longitudinal Data Analysis
P Value [3]	0.306
Mean Difference (Final Values) [4]	-3.10
95% Confidence Interval	-9.04 to 2.84

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	Triglycerides (mg/dL)
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[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 Other Lipid, Lipoprotein, Apolipoprotein and High-sensitivity C-reactive Protein (Hs-CRP)Levels

Groups [1]	All groups
Method [2]	Longitudinal Data Analysis
P Value [3]	0.111
Mean Difference (Final Values) [4]	-2.15
95% Confidence Interval	-4.79 to 0.49

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	High-Density Lipoprotein Cholesterol
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[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 4 for Percent Change From Baseline in Other Lipid, Lipoprotein, Apolipoprotein and High-sensitivity C-reactive Protein (Hs-CRP)Levels

Groups [1]	All groups
Method [2]	Longitudinal Data Analysis
P Value [3]	<0.001
Mean Difference (Final Values) [4]	-11.98
95% Confidence Interval	-16.10 to -7.86

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	Non High-Density Liproprotein Cholesterol
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[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 5 for Percent Change From Baseline in Other Lipid, Lipoprotein, Apolipoprotein and High-sensitivity C-reactive Protein (Hs-CRP)Levels

Groups [1]	All groups
[2]	

Method	Longitudinal Data Analysis
P Value [3]	<0.001
Mean Difference (Final Values) [4]	-13.25
95% Confidence Interval	-18.36 to -8.13

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	LDL Cholesterol/HDL Cholesterol
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[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 6 for Percent Change From Baseline in Other Lipid, Lipoprotein, Apolipoprotein and High-sensitivity C-reactive Protein (Hs-CRP)Levels

Groups [1]	All groups
Method [2]	Longitudinal Data Analysis
P Value [3]	0.002
Mean Difference (Final Values) [4]	-6.45
95% Confidence Interval	-10.53 to -2.36

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	Total Cholesterol/HDL Cholesterol
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[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 7 for Percent Change From Baseline in Other Lipid, Lipoprotein, Apolipoprotein and High-sensitivity C-reactive Protein (Hs-CRP)Levels

Groups [1]	All groups
Method [2]	Longitudinal Data Analysis
P Value [3]	0.001
Mean Difference (Final Values) [4]	-9.52

95% Confidence Interval	-15.30 to -3.75

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	Non-HDL Cholestrol/HDL Cholesterol
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[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 8 for Percent Change From Baseline in Other Lipid, Lipoprotein, Apolipoprotein and High-sensitivity C-reactive Protein (Hs-CRP)Levels

Groups [1]	All groups
Method [2]	Longitudinal Data Analysis
P Value [3]	<0.001
Mean Difference (Final Values) [4]	-9.41
95% Confidence Interval	-12.74 to -6.08

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	Apolipoprotein B (Apo B)
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[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 9 for Percent Change From Baseline in Other Lipid, Lipoprotein, Apolipoprotein and High-sensitivity C-reactive Protein (Hs-CRP)Levels

Groups [1]	All groups
Method [2]	Longitudinal Data Analysis
P Value [3]	0.102
Mean Difference (Final Values) [4]	-1.82
95% Confidence Interval	-3.99 to 0.36

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	Apolipoprotein A-I (Apo A-I)
[2]	Other relevant method information, such as adjustments or degrees of freedom:

	No text entered.
[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 10 for Percent Change From Baseline in Other Lipid, Lipoprotein, Apolipoprotein and High-sensitivity C-reactive Protein (Hs-CRP)Levels

Groups [1]	All groups
Method [2]	Longitudinal Data Analysis
P Value [3]	<0.001
Mean Difference (Final Values) [4]	-7.54
95% Confidence Interval	-11.25 to -3.83

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	Apolipoprotein B/Apo A-I
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[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 11 for Percent Change From Baseline in Other Lipid, Lipoprotein, Apolipoprotein and High-sensitivity C-reactive Protein (Hs-CRP)Levels

Groups [1]	All groups
Method [2]	Longitudinal Data Analysis
P Value [3]	0.861
Mean Difference (Final Values) [4]	-1.08
95% Confidence Interval	-13.13 to 10.97

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	hs-C-Reactive Protein
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[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	All participants randomized were treated and had safety follow up.

Reporting Groups

	Description
Rosuva 5 mg + EZ 10 mg	Participants who received open label rosuvastatin 5 mg tablets once daily for 4 to 5 weeks then received 10 mg ezetimibe tablets once daily plus 5mg rosuvastatin for an additional 6 weeks.
Rosuva 10 mg	Participants who received open label rosuvastatin 5 mg tablets once daily for 4 to 5 weeks then received rosuvastatin 10 mg once daily for 6 additional weeks.
Rosuva 10 mg + EZ 10 mg	Participants who received open label rosuvastatin 10 mg tablets once daily for 4 to 5 weeks then received 10 mg ezetimibe tablets once daily plus 10 mg rosuvastatin for an additional 6 weeks.
Rosuva 20 mg	Participants who received rosuvastatin 10 mg tablets once daily for 4 to 5 weeks then received rosuvastatin 20 mg once daily for 6 additional weeks.

Serious Adverse Events

	Rosuva 5 mg + EZ 10 mg	Rosuva 10 mg	Rosuva 10 mg + EZ 10 mg	Rosuva 20 mg
Total, serious adverse events				
# participants affected / at risk	**0/99 (0.00%)**	**1/98 (1.02%)**	**0/122 (0.00%)**	**1/121 (0.83%)**
Cardiac disorders				
Sick sinus syndrome † 1				
# participants affected / at risk	**0/99 (0.00%)**	**0/98 (0.00%)**	**0/122 (0.00%)**	**1/121 (0.83%)**
# events	**0**	**0**	**0**	**1**
Injury, poisoning and procedural complications				
Tendon rupture † 1				
# participants affected / at risk	**0/99 (0.00%)**	**1/98 (1.02%)**	**0/122 (0.00%)**	**0/121 (0.00%)**
# events	**0**	**1**	**0**	**0**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA 13.0

Other Adverse Events

Hide Other Adverse Events

Time Frame	No text entered.

Additional Description	All participants randomized were treated and had safety follow up.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Rosuva 5 mg + EZ 10 mg	Participants who received open label rosuvastatin 5 mg tablets once daily for 4 to 5 weeks then received 10 mg ezetimibe tablets once daily plus 5mg rosuvastatin for an additional 6 weeks.
Rosuva 10 mg	Participants who received open label rosuvastatin 5 mg tablets once daily for 4 to 5 weeks then received rosuvastatin 10 mg once daily for 6 additional weeks.
Rosuva 10 mg + EZ 10 mg	Participants who received open label rosuvastatin 10 mg tablets once daily for 4 to 5 weeks then received 10 mg ezetimibe tablets once daily plus 10 mg rosuvastatin for an additional 6 weeks.
Rosuva 20 mg	Participants who received rosuvastatin 10 mg tablets once daily for 4 to 5 weeks then received rosuvastatin 20 mg once daily for 6 additional weeks.

Other Adverse Events

	Rosuva 5 mg + EZ 10 mg	Rosuva 10 mg	Rosuva 10 mg + EZ 10 mg	Rosuva 20 mg
Total, other (not including serious) adverse events				
# participants affected / at risk	**0/99 (0.00%)**	**0/98 (0.00%)**	**0/122 (0.00%)**	**0/121 (0.00%)**

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.

Results Point of Contact:

Name/Title: Senior Vice President, Global Clinical Development
Organization: Merck Sharp & Dohme Corp
phone: 1-800-672-6372
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Publications of Results:

Bays HE, Davidson MH, Massaad R, Flaim D, Lowe RS, Tershakovec AM, Jones-Burton C. Safety and efficacy of ezetimibe added on to rosuvastatin 5 or 10 mg versus up-titration of rosuvastatin in patients with hypercholesterolemia (the ACTE Study). Am J Cardiol. 2011 Aug 15;108(4):523-30. doi: 10.1016/j.amjcard.2011.03.079. Epub 2011 May 17.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00783263 History of Changes
Other Study ID Numbers:	0653-139, 2008_567
Study First Received:	October 30, 2008
Results First Received:	August 10, 2011
Last Updated:	January 19, 2015
Health Authority:	United States: Food and Drug Administration

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