Study of Extended Release Niacin/Laropiprant on Lipids (0524A-067)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

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

ClinicalTrials.gov Identifier:
NCT00479388

First received: May 24, 2007
Last updated: February 20, 2015
Last verified: February 2015
History of Changes

Purpose

This is a 12-Week clinical trial in patients with Primary hypercholesterolemia or mixed dyslipidemia to study the effects of ER niacin/laropiprant on lipids.

Condition	Intervention	Phase
Primary Hypercholesterolemia Mixed Dyslipidemia	Drug: Comparator: simvastatin Drug: niacin (+) laropiprant Drug: Comparator: atorvastatin calcium	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 Group, 12 Week Study to Evaluate the Efficacy and Safety of Extended-release (ER) Niacin/Laropiprant in Patients With Primary Hypercholesterolemia or Mixed Dyslipidemia.

Resource links provided by NLM:

MedlinePlus related topics: Cholesterol

Drug Information available for: Niacin Niacinamide Simvastatin Atorvastatin Atorvastatin calcium

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 Cholesterol at Week 12 [Time Frame: Baseline and 12 Weeks] [Designated as safety issue: No]

Secondary Outcome Measures:

- Percent Change From Baseline in High Density Lipoprotein Cholesterol at Week 12 [Time Frame: Baseline and 12 Weeks] [Designated as safety issue: Yes]
- Percent Change From Baseline in Triglycerides at Week 12 [Time Frame: Baseline and 12 Weeks] [Designated as safety issue: No]

Enrollment:	1216
Study Start Date:	July 2007
Study Completion Date:	October 2008
Primary Completion Date:	July 2008 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
1 One tablet of ER niacin/ laropiprant (1g) + one tablet of the run-in statin dose, titrating up to ER niacin/laropiprant (2g) at Week 4 for an additional 8 weeks, with no adjustments to the run-in statin dose.	Drug: niacin (+) laropiprant One tablet of ER niacin/ laropiprant (1g); titrating up to ER niacin/laropiprant (2g) at Week 4 for an additional 8 weeks, with no adjustments to the run-in statin dose. Other Name: MK0524A
Active Comparator: 2 Stable dose of simvastatin or atorvastatin (20mg to 40mg) for 12 weeks.	Drug: Comparator: simvastatin simvastatin (20mg to 40mg) for 12 weeks. Other Name: Zocor® Drug: Comparator: atorvastatin calcium atorvastatin calcium (20mg to 40mg) for 12 weeks. Other Name: atorvastatin

Eligibility

Ages Eligible for Study:	18 Years to 80 Years
Genders Eligible for Study:	Both
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- Patients 18 to 80 years of age with Primary hypercholesterolemia or mixed dyslipidemia
- Patients will be eligible for the study if their LDL-C values are within protocol specified range and meet other entry criteria

Exclusion Criteria:

- Patient whose LDL-C values are not within protocol specified range

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: NCT00479388

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)

Publications:

Shah S, Ceska R, Gil-Extremera B, Paolini JF, Giezek H, Vandormael K, Mao A, McCrary Sisk C, Maccubbin D. Efficacy and safety of extended-release niacin/laropiprant plus statin vs. doubling the dose of statin in patients with primary hypercholesterolaemia or mixed dyslipidaemia. Int J Clin Pract. 2010 May;64(6):727-38. doi: 10.1111/j.1742-1241.2010.02370.x.

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

Bays HE, Shah A, Lin J, Sisk CM, Dong Q, Maccubbin D. Consistency of extended-release niacin/laropiprant effects on Lp(a), ApoB, non-HDL-C, Apo A1, and ApoB/ApoA1 ratio across patient subgroups. Am J Cardiovasc Drugs. 2012 Jun 1;12(3):197-206. doi: 10.2165/11631530-000000000-00000.

Bays H, Shah A, Dong Q, McCrary Sisk C, Maccubbin D. Extended-release niacin/laropiprant lipid-altering consistency across patient subgroups. Int J Clin Pract. 2011 Apr;65(4):436-45. doi: 10.1111/j.1742-1241.2010.02620.x.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00479388 History of Changes
Other Study ID Numbers:	0524A-067 2007_521
Study First Received:	May 24, 2007
Results First Received:	June 9, 2009
Last Updated:	February 20, 2015
Health Authority:	Canada: Health Canada

Additional relevant MeSH terms:

Dyslipidemias	Enzyme Inhibitors
Hypercholesterolemia	Growth Substances
Hyperlipidemias	Hydroxymethylglutaryl-CoA Reductase Inhibitors
Lipid Metabolism Disorders	Hypolipidemic Agents
Metabolic Diseases	Lipid Regulating Agents
Atorvastatin	Micronutrients
Niacin	Molecular Mechanisms of Pharmacological Action
Niacinamide	Pharmacologic Actions
Nicotinic Acids	Physiological Effects of Drugs
Simvastatin	Therapeutic Uses
Anticholesteremic Agents	Vasodilator Agents
Antimetabolites	Vitamin B Complex
Cardiovascular Agents	Vitamins

ClinicalTrials.gov processed this record on April 13, 2016

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History of Changes

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

Results First Received: June 9, 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:	Primary Hypercholesterolemia Mixed Dyslipidemia
Interventions:	Drug: Comparator: simvastatin Drug: niacin (+) laropiprant Drug: Comparator: atorvastatin calcium

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

First Patient In: 30-Jul-2007 Last Patient Last Visit: 10-Jul-2008

Investigators: 161 sites participated: Australia–5; Austria–4; Canada–11; Czech Republic–5; Denmark–4; France–10; Germany–24; Hungary–6; Israel–4; Italy–11; Netherlands–2; Norway–10; Poland–11; Russian Federation–7; South Africa–9; Spain–4; Sweden–17; United States–17

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment

Patients on atorvastatin (10mg) or simvastatin (10mg or 20mg) had a 2 week run-in of their statin. Naïve patients or patients on other statins were started on simvastatin (10 or 20mg) or atorvastatin (10mg) for a 6 week run-in. Patients were eligible to be randomized if their Visit 1 low density lipoprotein cholesterol values were above goal.

Reporting Groups

	Description
ER Niacin/Laropiprant + Run-in Statin	One tablet of ER niacin/ laropiprant (1g) + one tablet of the run-in statin dose, titrating up to ER niacin/laropiprant (2g) at Week 4 for an additional 8 weeks, with no adjustments to the run-in statin dose.
Run-in Statin Dose Doubled	Stable dose of simvastatin or atorvastatin (20mg to 40mg) for 12 weeks.

Participant Flow: Overall Study

	ER Niacin/Laropiprant + Run-in Statin	Run-in Statin Dose Doubled
STARTED	**606**	**610**
COMPLETED	**474**	**537**
NOT COMPLETED	**132**	**73**
Adverse Event	**90**	**45**
Lost to Follow-up	**0**	**2**
Protocol Violation	**10**	**9**
Withdrawal by Subject	**32**	**17**

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
ER Niacin/Laropiprant + Run-in Statin	One tablet of ER niacin/ laropiprant (1g) + one tablet of the run-in statin dose, titrating up to ER niacin/laropiprant (2g) at Week 4 for an additional 8 weeks, with no adjustments to the run-in statin dose.
Run-in Statin Dose Doubled	Stable dose of simvastatin or atorvastatin (20mg to 40mg) for 12 weeks.
Total	Total of all reporting groups

Baseline Measures

	ER Niacin/Laropiprant + Run-in Statin	Run-in Statin Dose Doubled	Total
Number of Participants [units: participants]	**606**	**610**	**1216**
Age [units: years]	**60.4 (9.7)**	**60.6 (9.8)**	**60.5 (9.7)**

Mean (Standard Deviation)			
Gender [units: participants]			
Female	**304**	**289**	**593**
Male	**302**	**321**	**623**
Coronary Heart Disease Risk Category by Goal [units: Participants]			
Low Risk at Goal	**27**	**26**	**53**
Low Risk Not at Goal	**16**	**14**	**30**
Multiple Risk at Goal	**91**	**82**	**173**
Multiple Risk Not at Goal	**92**	**71**	**163**
High Risk at Goal	**143**	**155**	**298**
High Risk Not at Goal	**237**	**262**	**499**
Lipid Modification Type/Dose at Run-in [units: participants]			
Simvastatin 10 mg	**218**	**233**	**451**
Simvastatin 20 mg	**259**	**268**	**527**
Atorvastatin 10 mg	**129**	**109**	**238**
Fasting Serum Glucose (FSG) [units: mg/dL] Mean (Standard Deviation)	**108.3 (27.2)**	**108.7 (27.7)**	**108.5 (27.4)**
High-density lipoprotein cholesterol [units: mg/dL] Mean (Standard Deviation)	**54.89 (14.45)**	**54.97 (13.91)**	**54.93 (14.17)**
Low-density lipoprotein cholesterol [units: mg/dL] Mean (Standard Deviation)	**117.55 (28.66)**	**115.82 (28.37)**	**116.68 (28.52)**
Triglycerides (TG) [units: mg/dL] Median (Full Range)	**136.00 (46.00 to 594.00)**	**124.00 (42.00 to 852.00)**	**130.00 (42.00 to 852.00)**

Outcome Measures

Hide All Outcome Measures

1. Primary: Percent Change From Baseline in Low Density Lipoprotein Cholesterol at Week 12 [Time Frame: Baseline and 12 Weeks]

Measure Type	Primary
Measure Title	Percent Change From Baseline in Low Density Lipoprotein Cholesterol at Week 12
Measure Description	No text entered.
Time Frame	Baseline and 12 Weeks
Safety Issue	No

Population Description

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

Reporting Groups

	Description
ER Niacin/Laropiprant + Run-in Statin	One tablet of ER niacin/ laropiprant (1g) + one tablet of the run-in statin dose, titrating up to ER niacin/laropiprant (2g) at Week 4 for an additional 8 weeks, with no adjustments to the run-in statin dose.
Run-in Statin Dose Doubled	Stable dose of simvastatin or atorvastatin (20mg to 40mg) for 12 weeks.

Measured Values

	ER Niacin/Laropiprant + Run-in Statin	**Run-in Statin Dose Doubled**
Number of Participants Analyzed [units: participants]	**572**	**595**
Percent Change From Baseline in Low Density Lipoprotein Cholesterol at Week 12 [units: Percent] Least Squares Mean (95% Confidence Interval)	**-10.0 (-12.6 to -7.4)**	**-5.5 (-7.4 to -3.5)**

Statistical Analysis 1 for Percent Change From Baseline in Low Density Lipoprotein Cholesterol at Week 12

Groups [1]	All groups
Method [2]	Repeated measures analysis
P Value [3]	0.006
Median Difference (Final Values) [4]	-4.5
Standard Error of the mean	(1.6)
95% Confidence Interval	-7.7 to -1.3

[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:
	Study times: 4, 8 and 12 weeks. Terms: treatment-by-time, gender-by-time, baseline LDL-C-by-time and concomitant statin group-by-time interaction.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

2. Secondary: Percent Change From Baseline in High Density Lipoprotein Cholesterol at Week 12 [Time Frame: Baseline and 12 Weeks]

Measure Type	Secondary
Measure Title	Percent Change From Baseline in High Density Lipoprotein Cholesterol at Week 12
Measure Description	No text entered.
Time Frame	Baseline and 12 Weeks
Safety Issue	Yes

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

Reporting Groups

	Description
ER Niacin/Laropiprant + Run-in Statin	One tablet of ER niacin/ laropiprant (1g) + one tablet of the run-in statin dose, titrating up to ER niacin/laropiprant (2g) at Week 4 for an additional 8 weeks, with no adjustments to the run-in statin dose.
Run-in Statin Dose Doubled	Stable dose of simvastatin or atorvastatin (20mg to 40mg) for 12 weeks.

Measured Values

	ER Niacin/Laropiprant + Run-in Statin	**Run-in Statin Dose Doubled**
Number of Participants Analyzed [units: participants]	**572**	**595**
Percent Change From Baseline in High Density Lipoprotein Cholesterol at Week 12 [units: Percent] Least Squares Mean (95% Confidence Interval)	**15.8 (13.8 to 17.8)**	**0.2 (-1.1 to 1.4)**

Statistical Analysis 1 for Percent Change From Baseline in High Density Lipoprotein Cholesterol at Week 12

Groups [1]	All groups
Method [2]	Repeated measures analysis
P Value [3]	<=0.001
Mean Difference (Final Values) [4]	15.6
Standard Error of the mean	(1.2)
95% Confidence Interval	13.4 to 17.9

[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:
	Study times: 4, 8 and 12 weeks. Terms: treatment-by-time, gender-by-time, baseline HDL-C-by-time and concomitant statin group-by-time interaction.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:

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

3. Secondary: Percent Change From Baseline in Triglycerides at Week 12 [Time Frame: Baseline and 12 Weeks]

Measure Type	Secondary
Measure Title	Percent Change From Baseline in Triglycerides at Week 12
Measure Description	No text entered.
Time Frame	Baseline and 12 Weeks
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full Analysis Set With at Least one Post-Titration Visit Measurement

Reporting Groups

	Description
ER Niacin/Laropiprant + Run-in Statin	One tablet of ER niacin/ laropiprant (1g) + one tablet of the run-in statin dose, titrating up to ER niacin/laropiprant (2g) at Week 4 for an additional 8 weeks, with no adjustments to the run-in statin dose.
Run-in Statin Dose Doubled	Stable dose of simvastatin or atorvastatin (20mg to 40mg) for 12 weeks.

Measured Values

	ER Niacin/Laropiprant + Run-in Statin	**Run-in Statin Dose Doubled**
Number of Participants Analyzed [units: participants]	**515**	**571**
Percent Change From Baseline in Triglycerides at Week 12 [units: Percent] Median (95% Confidence Interval)	**-17.6 (-21.0 to -14.2)**	**-4.0 (-7.2 to -0.9)**

Statistical Analysis 1 for Percent Change From Baseline in Triglycerides at Week 12

Groups [1]	All groups
Method [2]	Repeated measures analysis
P Value [3]	<=0.001
Mean Difference (Final Values) [4]	-15.4
95% Confidence Interval	-19.2 to -11.7

[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:
	ANCOVA model based on Tukey's normalized ranks with term for treatment, gender, concomitant statin group and Tukey's normal score of baseline.
[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
ER Niacin/Laropiprant + Run-in Statin	One tablet of ER niacin/ laropiprant (1g) + one tablet of the run-in statin dose, titrating up to ER niacin/laropiprant (2g) at Week 4 for an additional 8 weeks, with no adjustments to the run-in statin dose.
Run-in Statin Dose Doubled	Stable dose of simvastatin or atorvastatin (20mg to 40mg) for 12 weeks.

Serious Adverse Events

	ER Niacin/Laropiprant + Run-in Statin	Run-in Statin Dose Doubled
Total, serious adverse events		
# participants affected	**14**	**8**
Cardiac disorders		
Acute coronary syndrome * 1		
# participants affected / at risk	**1/602 (0.17%)**	**0/609 (0.00%)**
Acute myocardial infarction † 1		
# participants affected / at risk	**1/602 (0.17%)**	**0/609 (0.00%)**
Cardiac failure congestive * 1		
# participants affected / at risk	**1/602 (0.17%)**	**0/609 (0.00%)**
Eye disorders		
Eye discharge * 1		
# participants affected / at risk	**1/602 (0.17%)**	**0/609 (0.00%)**
General disorders		

Chest pain [*1]		
# participants affected / at risk	**0/602 (0.00%)**	**1/609 (0.16%)**
Non-cardiac chest pain [*1]		
# participants affected / at risk	**1/602 (0.17%)**	**0/609 (0.00%)**
Immune system disorders		
Drug hypersensitivity [*1]		
# participants affected / at risk	**1/602 (0.17%)**	**0/609 (0.00%)**
Oral herpes [*1]		
# participants affected / at risk	**1/602 (0.17%)**	**0/609 (0.00%)**
Infections and infestations		
Acute sinusitis [*1]		
# participants affected / at risk	**1/602 (0.17%)**	**0/609 (0.00%)**
Wound sepsis [*1]		
# participants affected / at risk	**1/602 (0.17%)**	**0/609 (0.00%)**
Musculoskeletal and connective tissue disorders		
Osteoarthritis [*1]		
# participants affected / at risk	**0/602 (0.00%)**	**1/609 (0.16%)**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Brain neoplasm [*1]		
# participants affected / at risk	**1/602 (0.17%)**	**0/609 (0.00%)**
Breast cancer [*1]		
# participants affected / at risk	**0/602 (0.00%)**	**1/609 (0.16%)**
Nervous system disorders		
Amnesia [*1]		
# participants affected / at risk	**0/602 (0.00%)**	**1/609 (0.16%)**
Cerebral haemorrhage [*1]		
# participants affected / at risk	**0/602 (0.00%)**	**1/609 (0.16%)**
Transient ischaemic attack [*1]		
# participants affected / at risk	**0/602 (0.00%)**	**1/609 (0.16%)**
Reproductive system and breast disorders		
Ovarian cyst [*1]		
# participants affected / at risk	**1/602 (0.17%)**	**0/609 (0.00%)**
Respiratory, thoracic and mediastinal disorders		
Bronchospasm [*1]		
# participants affected / at risk	**0/602 (0.00%)**	**1/609 (0.16%)**
Pulmonary embolism [*1]		
# participants affected / at risk	**0/602 (0.00%)**	**1/609 (0.16%)**
Vascular disorders		
Flushing [*1]		
# participants affected / at risk	**1/602 (0.17%)**	**0/609 (0.00%)**

Hypotension * 1		
# participants affected / at risk	**1/602 (0.17%)**	**0/609 (0.00%)**
Peripheral ischaemia * 1		
# participants affected / at risk	**1/602 (0.17%)**	**0/609 (0.00%)**

† Events were collected by systematic assessment
* Events were collected by non-systematic assessment
1 Term from vocabulary, MedDRA 11.0

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	0%

Reporting Groups

	Description
ER Niacin/Laropiprant + Run-in Statin	One tablet of ER niacin/ laropiprant (1g) + one tablet of the run-in statin dose, titrating up to ER niacin/laropiprant (2g) at Week 4 for an additional 8 weeks, with no adjustments to the run-in statin dose.
Run-in Statin Dose Doubled	Stable dose of simvastatin or atorvastatin (20mg to 40mg) for 12 weeks.

Other Adverse Events

	ER Niacin/Laropiprant + Run-in Statin	**Run-in Statin Dose Doubled**
Total, other (not including serious) adverse events		
# participants affected	**249**	**172**
Blood and lymphatic system disorders		
Anaemia * 1		
# participants affected / at risk	**0/602 (0.00%)**	**1/609 (0.16%)**
Neutropenia * 1		
# participants affected / at risk	**0/602 (0.00%)**	**2/609 (0.33%)**
Splenomegaly * 1		
# participants affected / at risk	**0/602 (0.00%)**	**1/609 (0.16%)**
Cardiac disorders		
Angina pectoris * 1		
# participants affected / at risk	**1/602 (0.17%)**	**1/609 (0.16%)**
Arrhythmia * 1		

# participants affected / at risk	0/602 (0.00%)	1/609 (0.16%)
Cardiac discomfort [*1]		
# participants affected / at risk	1/602 (0.17%)	0/609 (0.00%)
Palpitations [*1]		
# participants affected / at risk	1/602 (0.17%)	2/609 (0.33%)
Supraventricular extrasystoles [*1]		
# participants affected / at risk	1/602 (0.17%)	0/609 (0.00%)
Tachycardia [*1]		
# participants affected / at risk	0/602 (0.00%)	1/609 (0.16%)
Ear and labyrinth disorders		
Tinnitus [*1]		
# participants affected / at risk	0/602 (0.00%)	1/609 (0.16%)
Vertigo [*1]		
# participants affected / at risk	1/602 (0.17%)	4/609 (0.66%)
Eye disorders		
Cataract [*1]		
# participants affected / at risk	0/602 (0.00%)	1/609 (0.16%)
Conjunctivitis [*1]		
# participants affected / at risk	1/602 (0.17%)	4/609 (0.66%)
Dry eye [*1]		
# participants affected / at risk	1/602 (0.17%)	0/609 (0.00%)
Eye inflammation [*1]		
# participants affected / at risk	1/602 (0.17%)	0/609 (0.00%)
Eye irritation [*1]		
# participants affected / at risk	1/602 (0.17%)	0/609 (0.00%)
Eyelid oedema [*1]		
# participants affected / at risk	1/602 (0.17%)	0/609 (0.00%)
Lacrimation increased [*1]		
# participants affected / at risk	1/602 (0.17%)	0/609 (0.00%)
Retinal artery thrombosis [*1]		
# participants affected / at risk	0/602 (0.00%)	1/609 (0.16%)
Vision blurred [*1]		
# participants affected / at risk	0/602 (0.00%)	1/609 (0.16%)
Visual disturbance [*1]		
# participants affected / at risk	1/602 (0.17%)	0/609 (0.00%)
Gastrointestinal disorders		
Abdominal distension [*1]		
# participants affected / at risk	0/602 (0.00%)	1/609 (0.16%)
Abdominal pain [*1]		
# participants affected / at risk	6/602 (1.00%)	4/609 (0.66%)
Abdominal pain lower [*1]		

# participants affected / at risk	1/602 (0.17%)	0/609 (0.00%)
Abdominal pain upper [*1]		
# participants affected / at risk	12/602 (1.99%)	4/609 (0.66%)
Anal fissure [*1]		
# participants affected / at risk	0/602 (0.00%)	2/609 (0.33%)
Cheilitis [*1]		
# participants affected / at risk	0/602 (0.00%)	1/609 (0.16%)
Constipation [*1]		
# participants affected / at risk	1/602 (0.17%)	6/609 (0.99%)
Diarrhoea [*1]		
# participants affected / at risk	16/602 (2.66%)	4/609 (0.66%)
Dry mouth [*1]		
# participants affected / at risk	6/602 (1.00%)	0/609 (0.00%)
Duodenitis [*1]		
# participants affected / at risk	2/602 (0.33%)	0/609 (0.00%)
Dyspepsia [*1]		
# participants affected / at risk	7/602 (1.16%)	5/609 (0.82%)
Dysphagia [*1]		
# participants affected / at risk	0/602 (0.00%)	3/609 (0.49%)
Eructation [*1]		
# participants affected / at risk	1/602 (0.17%)	0/609 (0.00%)
Flatulence [*1]		
# participants affected / at risk	1/602 (0.17%)	3/609 (0.49%)
Gastritis [*1]		
# participants affected / at risk	2/602 (0.33%)	1/609 (0.16%)
Gastrooesophageal reflux disease [*1]		
# participants affected / at risk	1/602 (0.17%)	0/609 (0.00%)
Haemorrhoids [*1]		
# participants affected / at risk	0/602 (0.00%)	2/609 (0.33%)
Hiatus hernia [*1]		
# participants affected / at risk	1/602 (0.17%)	0/609 (0.00%)
Hypoaesthesia oral [*1]		
# participants affected / at risk	0/602 (0.00%)	1/609 (0.16%)
Nausea [†1]		
# participants affected / at risk	20/602 (3.32%)	9/609 (1.48%)
Oral disorder [*1]		
# participants affected / at risk	0/602 (0.00%)	1/609 (0.16%)
Stomach discomfort [*1]		
# participants affected / at risk	1/602 (0.17%)	0/609 (0.00%)
Stomatitis [*1]		
# participants affected / at risk	1/602 (0.17%)	0/609 (0.00%)
[*1]		

Toothache		
# participants affected / at risk	**2/602 (0.33%)**	**0/609 (0.00%)**
Vomiting [*1]		
# participants affected / at risk	**7/602 (1.16%)**	**4/609 (0.66%)**
General disorders		
Asthenia [*1]		
# participants affected / at risk	**2/602 (0.33%)**	**1/609 (0.16%)**
Chest discomfort [*1]		
# participants affected / at risk	**0/602 (0.00%)**	**1/609 (0.16%)**
Chest pain [*1]		
# participants affected / at risk	**1/602 (0.17%)**	**1/609 (0.16%)**
Chills [*1]		
# participants affected / at risk	**1/602 (0.17%)**	**1/609 (0.16%)**
Discomfort [*1]		
# participants affected / at risk	**2/602 (0.33%)**	**0/609 (0.00%)**
Fatigue [*1]		
# participants affected / at risk	**1/602 (0.17%)**	**2/609 (0.33%)**
Feeling cold [†1]		
# participants affected / at risk	**0/602 (0.00%)**	**1/609 (0.16%)**
Feeling hot [*1]		
# participants affected / at risk	**9/602 (1.50%)**	**3/609 (0.49%)**
Influenza like illness [*1]		
# participants affected / at risk	**0/602 (0.00%)**	**1/609 (0.16%)**
Malaise [*1]		
# participants affected / at risk	**1/602 (0.17%)**	**2/609 (0.33%)**
Non-cardiac chest pain [*1]		
# participants affected / at risk	**1/602 (0.17%)**	**1/609 (0.16%)**
Oedema peripheral [*1]		
# participants affected / at risk	**2/602 (0.33%)**	**3/609 (0.49%)**
Pain [*1]		
# participants affected / at risk	**2/602 (0.33%)**	**0/609 (0.00%)**
Pyrexia [*1]		
# participants affected / at risk	**2/602 (0.33%)**	**0/609 (0.00%)**
Hepatobiliary disorders		
Cholelithiasis [*1]		
# participants affected / at risk	**0/602 (0.00%)**	**1/609 (0.16%)**
Immune system disorders		
Drug hypersensitivity [*1]		
# participants affected / at risk	**1/602 (0.17%)**	**0/609 (0.00%)**
Infections and infestations		
Acute tonsillitis [*1]		

# participants affected / at risk	0/602 (0.00%)	2/609 (0.33%)
Balanitis candida [*1]		
# participants affected / at risk	1/602 (0.17%)	0/609 (0.00%)
Breast abscess [*1]		
# participants affected / at risk	0/602 (0.00%)	1/609 (0.16%)
Bronchitis [*1]		
# participants affected / at risk	11/602 (1.83%)	5/609 (0.82%)
Bronchitis bacterial [*1]		
# participants affected / at risk	0/602 (0.00%)	1/609 (0.16%)
Bronchopneumonia [*1]		
# participants affected / at risk	1/602 (0.17%)	1/609 (0.16%)
Candidiasis [*1]		
# participants affected / at risk	0/602 (0.00%)	1/609 (0.16%)
Cystitis [*1]		
# participants affected / at risk	2/602 (0.33%)	2/609 (0.33%)
Ear infection [*1]		
# participants affected / at risk	0/602 (0.00%)	1/609 (0.16%)
Furuncle [*1]		
# participants affected / at risk	1/602 (0.17%)	0/609 (0.00%)
Gastroenteritis [*1]		
# participants affected / at risk	3/602 (0.50%)	6/609 (0.99%)
Herpes simplex [*1]		
# participants affected / at risk	1/602 (0.17%)	0/609 (0.00%)
Herpes zoster [*1]		
# participants affected / at risk	2/602 (0.33%)	1/609 (0.16%)
Influenza [†1]		
# participants affected / at risk	4/602 (0.66%)	3/609 (0.49%)
Mycoplasma infection [*1]		
# participants affected / at risk	0/602 (0.00%)	1/609 (0.16%)
Nasopharyngitis [†1]		
# participants affected / at risk	13/602 (2.16%)	15/609 (2.46%)
Oral herpes [*1]		
# participants affected / at risk	1/602 (0.17%)	0/609 (0.00%)
Otitis media [*1]		
# participants affected / at risk	2/602 (0.33%)	0/609 (0.00%)
Pharyngitis [*1]		
# participants affected / at risk	1/602 (0.17%)	0/609 (0.00%)
Pulpitis dental [*1]		
# participants affected / at risk	0/602 (0.00%)	1/609 (0.16%)
Respiratory tract infection [*1]		
# participants affected / at risk	2/602 (0.33%)	2/609 (0.33%)
[*1]		

Rhinitis		
# participants affected / at risk	**1/602 (0.17%)**	**0/609 (0.00%)**
Sinusitis [*1]		
# participants affected / at risk	**0/602 (0.00%)**	**2/609 (0.33%)**
Tonsillitis [†1]		
# participants affected / at risk	**0/602 (0.00%)**	**1/609 (0.16%)**
Tooth infection [*1]		
# participants affected / at risk	**0/602 (0.00%)**	**1/609 (0.16%)**
Tracheobronchitis [*1]		
# participants affected / at risk	**1/602 (0.17%)**	**2/609 (0.33%)**
Upper respiratory tract infection [*1]		
# participants affected / at risk	**5/602 (0.83%)**	**6/609 (0.99%)**
Urinary tract infection [*1]		
# participants affected / at risk	**2/602 (0.33%)**	**3/609 (0.49%)**
Injury, poisoning and procedural complications		
Animal bite [*1]		
# participants affected / at risk	**1/602 (0.17%)**	**0/609 (0.00%)**
Arthropod bite [*1]		
# participants affected / at risk	**0/602 (0.00%)**	**1/609 (0.16%)**
Fibula fracture [*1]		
# participants affected / at risk	**0/602 (0.00%)**	**1/609 (0.16%)**
Joint sprain [†1]		
# participants affected / at risk	**1/602 (0.17%)**	**0/609 (0.00%)**
Tooth fracture [*1]		
# participants affected / at risk	**1/602 (0.17%)**	**0/609 (0.00%)**
Investigations		
Blood pressure increased [*1]		
# participants affected / at risk	**1/602 (0.17%)**	**2/609 (0.33%)**
Gastric pH decreased [*1]		
# participants affected / at risk	**0/602 (0.00%)**	**1/609 (0.16%)**
Liver palpable subcostal [†1]		
# participants affected / at risk	**1/602 (0.17%)**	**0/609 (0.00%)**
Pulse abnormal [*1]		
# participants affected / at risk	**0/602 (0.00%)**	**1/609 (0.16%)**
Weight increased [*1]		
# participants affected / at risk	**0/602 (0.00%)**	**1/609 (0.16%)**
Alanine aminotransferase increased [*1]		
# participants affected / at risk	**7/602 (1.16%)**	**0/609 (0.00%)**
Aspartate aminotransferase increased [*1]		
# participants affected / at risk	**5/602 (0.83%)**	**1/609 (0.16%)**
Blood creatine phosphokinase increased [*1]		

# participants affected / at risk	4/602 (0.66%)	0/609 (0.00%)
Blood creatinine increased * 1		
# participants affected / at risk	1/602 (0.17%)	0/609 (0.00%)
Blood glucose increased * 1		
# participants affected / at risk	9/602 (1.50%)	0/609 (0.00%)
Blood lactate dehydrogenase increased * 1		
# participants affected / at risk	1/602 (0.17%)	0/609 (0.00%)
Blood potassium increased * 1		
# participants affected / at risk	0/602 (0.00%)	1/609 (0.16%)
Gamma-glutamyltransferase increased * 1		
# participants affected / at risk	2/602 (0.33%)	1/609 (0.16%)
Metabolism and nutrition disorders		
Gout * 1		
# participants affected / at risk	1/602 (0.17%)	0/609 (0.00%)
Hyperkalaemia * 1		
# participants affected / at risk	0/602 (0.00%)	1/609 (0.16%)
Hyponatraemia * 1		
# participants affected / at risk	0/602 (0.00%)	1/609 (0.16%)
Impaired fasting glucose * 1		
# participants affected / at risk	0/602 (0.00%)	1/609 (0.16%)
Type 2 diabetes mellitus * 1		
# participants affected / at risk	4/602 (0.66%)	1/609 (0.16%)
Musculoskeletal and connective tissue disorders		
Arthralgia * 1		
# participants affected / at risk	2/602 (0.33%)	3/609 (0.49%)
Back pain * 1		
# participants affected / at risk	3/602 (0.50%)	2/609 (0.33%)
Bursitis * 1		
# participants affected / at risk	1/602 (0.17%)	0/609 (0.00%)
Joint contracture * 1		
# participants affected / at risk	0/602 (0.00%)	1/609 (0.16%)
Muscle fatigue * 1		
# participants affected / at risk	0/602 (0.00%)	1/609 (0.16%)
Muscle spasms * 1		
# participants affected / at risk	3/602 (0.50%)	0/609 (0.00%)
Muscular weakness * 1		
# participants affected / at risk	0/602 (0.00%)	1/609 (0.16%)
Musculoskeletal chest pain * 1		
# participants affected / at risk	1/602 (0.17%)	0/609 (0.00%)
Musculoskeletal discomfort * 1		
# participants affected / at risk	3/602 (0.50%)	0/609 (0.00%)

Musculoskeletal pain [*1]		
# participants affected / at risk	**3/602 (0.50%)**	**0/609 (0.00%)**
Musculoskeletal stiffness [*1]		
# participants affected / at risk	**1/602 (0.17%)**	**0/609 (0.00%)**
Myalgia [*1]		
# participants affected / at risk	**6/602 (1.00%)**	**12/609 (1.97%)**
Neck pain [*1]		
# participants affected / at risk	**2/602 (0.33%)**	**0/609 (0.00%)**
Synovitis [*1]		
# participants affected / at risk	**0/602 (0.00%)**	**1/609 (0.16%)**
Tendonitis [*1]		
# participants affected / at risk	**0/602 (0.00%)**	**1/609 (0.16%)**
Torticollis [*1]		
# participants affected / at risk	**0/602 (0.00%)**	**1/609 (0.16%)**
Nervous system disorders		
Balance disorder [*1]		
# participants affected / at risk	**0/602 (0.00%)**	**1/609 (0.16%)**
Burning sensation [*1]		
# participants affected / at risk	**1/602 (0.17%)**	**0/609 (0.00%)**
Carpal tunnel syndrome [*1]		
# participants affected / at risk	**1/602 (0.17%)**	**0/609 (0.00%)**
Dizziness [*1]		
# participants affected / at risk	**9/602 (1.50%)**	**7/609 (1.15%)**
Headache [*1]		
# participants affected / at risk	**6/602 (1.00%)**	**11/609 (1.81%)**
Hypoaesthesia [*1]		
# participants affected / at risk	**2/602 (0.33%)**	**1/609 (0.16%)**
Lethargy [*1]		
# participants affected / at risk	**1/602 (0.17%)**	**1/609 (0.16%)**
Loss of consciousness [*1]		
# participants affected / at risk	**0/602 (0.00%)**	**1/609 (0.16%)**
Paraesthesia [*1]		
# participants affected / at risk	**12/602 (1.99%)**	**2/609 (0.33%)**
Post herpetic neuralgia [*1]		
# participants affected / at risk	**0/602 (0.00%)**	**1/609 (0.16%)**
Sciatica [*1]		
# participants affected / at risk	**2/602 (0.33%)**	**1/609 (0.16%)**
Somnolence [*1]		
# participants affected / at risk	**0/602 (0.00%)**	**1/609 (0.16%)**
Syncope [*1]		
# participants affected / at risk	**1/602 (0.17%)**	**0/609 (0.00%)**
[*1]		

Tremor		
# participants affected / at risk	**0/602 (0.00%)**	**1/609 (0.16%)**
Psychiatric disorders		
Anger [*1]		
# participants affected / at risk	**1/602 (0.17%)**	**0/609 (0.00%)**
Anxiety [*1]		
# participants affected / at risk	**1/602 (0.17%)**	**2/609 (0.33%)**
Depression [*1]		
# participants affected / at risk	**0/602 (0.00%)**	**1/609 (0.16%)**
Insomnia [*1]		
# participants affected / at risk	**3/602 (0.50%)**	**6/609 (0.99%)**
Renal and urinary disorders		
Dysuria [*1]		
# participants affected / at risk	**1/602 (0.17%)**	**0/609 (0.00%)**
Haematuria [*1]		
# participants affected / at risk	**0/602 (0.00%)**	**1/609 (0.16%)**
Nephrolithiasis [*1]		
# participants affected / at risk	**1/602 (0.17%)**	**1/609 (0.16%)**
Reproductive system and breast disorders		
Breast pain [*1]		
# participants affected / at risk	**0/602 (0.00%)**	**1/609 (0.16%)**
Menstruation delayed [*1]		
# participants affected / at risk	**0/602 (0.00%)**	**1/609 (0.16%)**
Respiratory, thoracic and mediastinal disorders		
Asthma [*1]		
# participants affected / at risk	**1/602 (0.17%)**	**0/609 (0.00%)**
Cough [*1]		
# participants affected / at risk	**3/602 (0.50%)**	**2/609 (0.33%)**
Dyspnoea exertional [*1]		
# participants affected / at risk	**1/602 (0.17%)**	**0/609 (0.00%)**
Epistaxis [*1]		
# participants affected / at risk	**2/602 (0.33%)**	**1/609 (0.16%)**
Pharyngeal oedema [*1]		
# participants affected / at risk	**1/602 (0.17%)**	**0/609 (0.00%)**
Wheezing [*1]		
# participants affected / at risk	**0/602 (0.00%)**	**1/609 (0.16%)**
Dandruff [*1]		
# participants affected / at risk	**0/602 (0.00%)**	**1/609 (0.16%)**
Skin and subcutaneous tissue disorders		
Acne [*1]		
# participants affected / at risk	**1/602 (0.17%)**	**0/609 (0.00%)**

Acrodermatitis [*1]		
# participants affected / at risk	**1/602 (0.17%)**	**0/609 (0.00%)**
Alopecia [*1]		
# participants affected / at risk	**1/602 (0.17%)**	**0/609 (0.00%)**
Dermatitis [*1]		
# participants affected / at risk	**2/602 (0.33%)**	**0/609 (0.00%)**
Dermatitis allergic [*1]		
# participants affected / at risk	**1/602 (0.17%)**	**0/609 (0.00%)**
Drug eruption [*1]		
# participants affected / at risk	**1/602 (0.17%)**	**1/609 (0.16%)**
Eczema [*1]		
# participants affected / at risk	**1/602 (0.17%)**	**1/609 (0.16%)**
Erythema [*1]		
# participants affected / at risk	**6/602 (1.00%)**	**3/609 (0.49%)**
Heat rash [*1]		
# participants affected / at risk	**0/602 (0.00%)**	**1/609 (0.16%)**
Hyperhidrosis [*1]		
# participants affected / at risk	**2/602 (0.33%)**	**0/609 (0.00%)**
Hypoaesthesia facial [*1]		
# participants affected / at risk	**1/602 (0.17%)**	**0/609 (0.00%)**
Night sweats [*1]		
# participants affected / at risk	**0/602 (0.00%)**	**1/609 (0.16%)**
Pigmentation disorder [*1]		
# participants affected / at risk	**1/602 (0.17%)**	**0/609 (0.00%)**
Pruritus [*1]		
# participants affected / at risk	**52/602 (8.64%)**	**10/609 (1.64%)**
Pruritus generalised [*1]		
# participants affected / at risk	**2/602 (0.33%)**	**0/609 (0.00%)**
Rash [*1]		
# participants affected / at risk	**11/602 (1.83%)**	**0/609 (0.00%)**
Rash erythematous [*1]		
# participants affected / at risk	**1/602 (0.17%)**	**2/609 (0.33%)**
Rash generalised [*1]		
# participants affected / at risk	**1/602 (0.17%)**	**0/609 (0.00%)**
Rash macular [*1]		
# participants affected / at risk	**0/602 (0.00%)**	**1/609 (0.16%)**
Rash pruritic [*1]		
# participants affected / at risk	**0/602 (0.00%)**	**1/609 (0.16%)**
Rosacea [*1]		
# participants affected / at risk	**0/602 (0.00%)**	**1/609 (0.16%)**
Seborrhoeic dermatitis [*1]		
# participants affected / at risk	**0/602 (0.00%)**	**1/609 (0.16%)**

Skin burning sensation * 1		
# participants affected / at risk	**3/602 (0.50%)**	**0/609 (0.00%)**
Skin discolouration * 1		
# participants affected / at risk	**1/602 (0.17%)**	**0/609 (0.00%)**
Skin irritation * 1		
# participants affected / at risk	**1/602 (0.17%)**	**1/609 (0.16%)**
Urticaria * 1		
# participants affected / at risk	**1/602 (0.17%)**	**2/609 (0.33%)**
Surgical and medical procedures		
Swelling face * 1		
# participants affected / at risk	**1/602 (0.17%)**	**0/609 (0.00%)**
Vascular disorders		
Blood pressure fluctuation * 1		
# participants affected / at risk	**0/602 (0.00%)**	**1/609 (0.16%)**
Flushing * 1		
# participants affected / at risk	**68/602 (11.30%)**	**9/609 (1.48%)**
Hypertension * 1		
# participants affected / at risk	**0/602 (0.00%)**	**1/609 (0.16%)**
Orthostatic hypotension * 1		
# participants affected / at risk	**1/602 (0.17%)**	**0/609 (0.00%)**
Phlebitis * 1		
# participants affected / at risk	**0/602 (0.00%)**	**1/609 (0.16%)**
Varicose vein * 1		
# participants affected / at risk	**1/602 (0.17%)**	**0/609 (0.00%)**

† Events were collected by systematic assessment
* Events were collected by non-systematic assessment
1 Term from vocabulary, MedDRA 11.0

Limitations and Caveats

Hide Limitations and Caveats

Limitations of the study, such as early termination leading to small numbers of participants analyzed and technical problems with measurement leading to unreliable or uninterpretable data

No text entered.

More Information

Hide More Information

Certain Agreements:

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

There **IS** an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

The agreement is:

☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **less than or equal to 60 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **more than 60 days but less than or equal to 180 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

☑ Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed.

Restriction Description: Merck agreements may vary with individual investigators, but will not prohibit any investigator from publishing. Merck supports the publication of results from all centers of a multi-center trial but requests that reports based on single-site data not precede the primary publication of the entire clinical trial.

Results Point of Contact:

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

Publications of Results:

Shah S, Ceska R, Gil-Extremera B, Paolini JF, Giezek H, Vandormael K, Mao A, McCrary Sisk C, Maccubbin D. Efficacy and safety of extended-release niacin/laropiprant plus statin vs. doubling the dose of statin in patients with primary hypercholesterolaemia or mixed dyslipidaemia. Int J Clin Pract. 2010 May;64(6):727-38. doi: 10.1111/j.1742-1241.2010.02370.x.

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

Bays HE, Shah A, Lin J, Sisk CM, Dong Q, Maccubbin D. Consistency of extended-release niacin/laropiprant effects on Lp(a), ApoB, non-HDL-C, Apo A1, and ApoB/ApoA1 ratio across patient subgroups. Am J Cardiovasc Drugs. 2012 Jun 1;12(3):197-206. doi: 10.2165/11631530-000000000-00000.

Bays H, Shah A, Dong Q, McCrary Sisk C, Maccubbin D. Extended-release niacin/laropiprant lipid-altering consistency across patient subgroups. Int J Clin Pract. 2011 Apr;65(4):436-45. doi: 10.1111/j.1742-1241.2010.02620.x.

Responsible Party:	Merck Sharp & Dohme Corp.
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Health Authority:	Canada: Health Canada

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