A Long-term Study of ERN/LRPT (Extended Release Niacin/Laropiprant [MK0524A]) in Patients With Dyslipidemia (0524A-102)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

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

ClinicalTrials.gov Identifier:
NCT00961636

First received: August 17, 2009
Last updated: January 29, 2015
Last verified: January 2015
History of Changes

Purpose

This study will evaluate the efficacy of laropiprant (LRPT) to reduce flushing symptoms beyond 6 months and will measure the impact of withdrawal of laropiprant in patients following 20 weeks of stable maintenance therapy.

Condition	Intervention	Phase
Dyslipidemia	Drug: ER niacin (+) laropiprant (ERN/LRPT) Drug: Extended-release niacin (ERN) Drug: Placebo to ERN/LRPT	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 Worldwide, Multicenter, Double-Blind, Randomized, Parallel, Placebo-Controlled Study to Evaluate the Long-term Efficacy, Safety and Tolerability of ERN/LRPT in Patients With Dyslipidemia

Resource links provided by NLM:

Drug Information available for: Niacin Niacinamide

U.S. FDA Resources

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

Primary Outcome Measures:

Number Participants With Days Per Week With Global Flushing Severity Score (GFSS) ≥4 Partitioned Into 6 Categories During the Postwithdrawal Period [Time Frame: Week 21 to Week 32] [Designated as safety issue: No]

Flushing symptoms were recorded using participant's response to the Global Flushing Severity Score (GFSS), which assessed the overall severity of the flushing experience, using a scale of 0 (no symptom) to 10 (extreme). The number of days/week was derived as: 7*(total number of days with GFSS ≥4 across Weeks 21-32 divided by the total number of days with nonmissing GFSS across the same period). The number of days/week with a GFSS ≥4 for each participant was listed in 1 of the following 6 categories: 0, >0 to 0.5, >0.5 to 1, >1 to 2, >2 to 3, and >3 days per week.

Secondary Outcome Measures:

- Number of Participants With Maximum GFSS ≥4 During the Post-withdrawal Period [Time Frame: Week 21 to Week 32] [Designated as safety issue: No]

  Flushing symptoms were recorded using participant's response to the Global Flushing Severity Score (GFSS), which assesses the overall severity of the flushing experience (including redness, warmth, tingling, or itching) using a scale with response categories of None, Mild, Moderate, Severe, and Extreme. The categories were supplemented with numbers 0 to 10 to allow for greater precision within each category (None=0, Mild=1-3, Moderate=4-6, Severe=7-9, Extreme=10). The daily response was recorded in the morning, and reflected the symptoms experienced during the previous 24 hours.

Enrollment:	1152
Study Start Date:	October 2009
Study Completion Date:	January 2011
Primary Completion Date:	January 2011 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: ERN/LRPT One 1g/20 mg tablet ERN/LRPT once daily for 4 weeks, then two 1g/20 mg tablets daily (2g/40 mg total) for 28 weeks	Drug: ER niacin (+) laropiprant (ERN/LRPT) One 1g/20 mg tablet ERN/LRPT once daily for 4 weeks, then two 1g/20 mg tablets daily (2g/40 mg total) for 28 weeks
Experimental: ERN/LRPT then ERN One 1g/20mg tablet ERN/LRPT once daily for 4 weeks, then two 1g/20 mg tablets daily (2g/40 mg total) for 16 weeks then Two 1g tablets ERN (2g total) once daily for 12 weeks.	Drug: ER niacin (+) laropiprant (ERN/LRPT) One 1g/20mg tablet ERN/LRPT once daily for 4 weeks, then two 1g/20 mg tablets daily (2g/40 mg total) for 16 weeks. Drug: Extended-release niacin (ERN) Two 1g tablets ERN (2g total) once daily for 12 weeks.
Placebo Comparator: Placebo One tablet placebo to ERN/LRPT once daily for 4 weeks, then two tablets placebo to ERN/LRPT daily for 28 weeks.	Drug: Placebo to ERN/LRPT One tablet placebo to ERN/LRPT once daily for 4 weeks, then two tablets placebo to ERN/LRPT daily for 28 weeks

Eligibility

Ages Eligible for Study:	18 Years to 75 Years
Genders Eligible for Study:	Both
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- Patient is a male, or a female who is unlikely to conceive, as indicated by meeting at least one of the following conditions: (a) Patient is a male. (b) Patient is a female of reproductive potential and either agrees to remain abstinent (if this form of birth control is accepted by local regulatory agencies and review committees as the sole method of birth control) or use (or have their partner use) 2 acceptable methods of birth control within the projected duration of the study.(c) Patient is a female who is not of reproductive potential and therefore eligible to participate in this study without requiring the use of contraception.
- Lipid-modifying therapy (LMT) is appropriate for the patient

- Patient meets one of the following criteria based on the National Cholesterol Education Program Adult Treatment Panel III guidelines : 1) High risk and is on a statin with LDL-cholesterol (LDL-C) <100 mg/dL or intolerant to statins with LDL-C <120 mg/dL; 2) Multiple risk with LDL-C <130 mg/dL; 3) Low risk with LDL-C <190 mg/dL
- Patient has triglyceride levels <500 mg/dL

Exclusion Criteria:

- Patient is pregnant, breast-feeding, or expecting to conceive
- Patient has a history of cancer within 5 years of screening (except certain skin and cervical cancers)
- Female patient plans to donate eggs during the study
- Male patient plans to donate sperm during the study
- Patient has or has a history of any condition, therapy, or lab abnormality that might confound the study results, interfere with participation for the full duration of the study, or make participation in the study not in the patient's best interest
- Patient has donated or received blood within 8 weeks of screening or plans to donate/receive blood during and 8 weeks after the study
- Patient is experiencing menopausal hot flashes
- Patient has chronic heart failure, uncontrolled cardiac arrhythmias, or poorly controlled hypertension
- Patient has type 1 or 2 diabetes and is poorly-controlled, newly diagnosed, has recently had repeated hypoglycemia, or is taking new or recently adjusted antidiabetic medication
- Patient has uncontrolled metabolic or endocrine disease that influences serum lipids or lipoproteins
- Patient has kidney disease
- Patient had active peptic ulcers within 3 months of screening
- Patient has a history of heart attack, stroke, heart bypass surgery, angina, or angioplasty within 3 months of screening
- Patient is human immunodeficiency virus (HIV) positive
- Patient is taking or has taken niacin >50 mg daily within 6 weeks of screening
- Patient has had a change to type or dose of LMT regimen within 6 weeks of Visit 1
- Patient is taking a statin and a fibrate at screening
- Patient is taking a long acting non-steroidal anti-inflammatory drug (NSAID), such as naproxen or aspirin >100 mg per day at screening
- Patient has arterial bleeding

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: NCT00961636

Sponsors and Collaborators

Merck Sharp & Dohme Corp.

Investigators

Study Director: Medical Monitor Merck Sharp & Dohme Corp.

More Information

Publications:

Maccubbin DL, Chen F, Anderson JW, Sirah W, McCrary Sisk C, Kher U, Olsson AG, Bays HE, Mitchel YB. Effectiveness and safety of laropiprant on niacin-induced flushing. Am J Cardiol. 2012 Sep 15;110(6):817-22. doi: 10.1016/j.amjcard.2012.05.009. Epub 2012 Jun 8.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00961636 History of Changes
Other Study ID Numbers:	0524A-102 2009_634
Study First Received:	August 17, 2009
Results First Received:	January 14, 2012
Last Updated:	January 29, 2015

Health Authority: United States: Food and Drug Administration

Additional relevant MeSH terms:

Dyslipidemias
Lipid Metabolism Disorders
Metabolic Diseases
Niacin
Niacinamide
Nicotinic Acids
Antimetabolites
Cardiovascular Agents
Growth Substances
Hypolipidemic Agents
Lipid Regulating Agents
Micronutrients
Molecular Mechanisms of Pharmacological Action
Pharmacologic Actions
Physiological Effects of Drugs
Therapeutic Uses
Vasodilator Agents
Vitamin B Complex
Vitamins

ClinicalTrials.gov processed this record on April 14, 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

A Long-term Study of ERN/LRPT (Extended Release Niacin/Laropiprant [MK0524A]) in Patients With Dyslipidemia (0524A-102)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

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

ClinicalTrials.gov Identifier:
NCT00961636

First received: August 17, 2009
Last updated: January 29, 2015
Last verified: January 2015
History of Changes

Results First Received: January 14, 2012

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:	Dyslipidemia
Interventions:	Drug: ER niacin (+) laropiprant (ERN/LRPT) Drug: Extended-release niacin (ERN) Drug: Placebo to ERN/LRPT

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
ERN/LRPT	One 1g/20 mg tablet Extended -release niacin (+) laropiprant (ERN/LRPT) once daily for 4 weeks, then two 1g/20 mg tablets daily (2g/40 mg total) for 28 weeks
ERN/LRPT Then ERN	One 1g/20mg tablet ERN/LRPT once daily for 4 weeks, then two 1g/20 mg tablets daily (2g/40 mg total) for 16 weeks then Two 1g tablets ERN (2g total) once daily for 12 weeks.
Placebo	One tablet placebo to ERN/LRPT once daily for 4 weeks, then two tablets placebo to ERN/LRPT daily for 28 weeks.

Participant Flow: Overall Study

	ERN/LRPT	ERN/LRPT Then ERN	Placebo
STARTED	463	456	233
COMPLETED	356	325	201
NOT COMPLETED	107	131	32
Adverse Event	35	54	13
Flushing Symptoms	29	46	3
Lost to Follow-up	2	3	1
Physician Decision	3	1	1
Protocol Violation	9	5	1
Withdrawal by Subject	29	22	13

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
ERN/LRPT	One 1g/20 mg tablet ERN/LRPT once daily for 4 weeks, then two 1g/20 mg tablets daily (2g/40 mg total) for 28 weeks
ERN/LRPT Then ERN	One 1g/20mg tablet ERN/LRPT once daily for 4 weeks, then two 1g/20 mg tablets daily (2g/40 mg total) for 16 weeks then Two 1g tablets ERN (2g total) once daily for 12 weeks.
Placebo	One tablet placebo to ERN/LRPT once daily for 4 weeks, then two tablets placebo to ERN/LRPT daily for 28 weeks.
Total	Total of all reporting groups

Baseline Measures

	ERN/LRPT	ERN/LRPT Then ERN	Placebo	Total
Number of Participants [units: participants]	463	456	233	1152

Age, Customized [units: Participants]				
< 65 years	**334**	**328**	**166**	**828**
>=65 years	**129**	**128**	**67**	**324**
Gender [units: participants]				
Female	**184**	**144**	**87**	**415**
Male	**279**	**312**	**146**	**737**

Outcome Measures

Hide All Outcome Measures

1. Primary: Number Participants With Days Per Week With Global Flushing Severity Score (GFSS) ≥4 Partitioned Into 6 Categories During the Postwithdrawal Period [Time Frame: Week 21 to Week 32]

Measure Type	Primary
Measure Title	Number Participants With Days Per Week With Global Flushing Severity Score (GFSS) ≥4 Partitioned Into 6 Categories During the Postwithdrawal Period
Measure Description	Flushing symptoms were recorded using participant's response to the Global Flushing Severity Score (GFSS), which assessed the overall severity of the flushing experience, using a scale of 0 (no symptom) to 10 (extreme). The number of days/week was derived as: 7*(total number of days with GFSS ≥4 across Weeks 21-32 divided by the total number of days with nonmissing GFSS across the same period). The number of days/week with a GFSS ≥4 for each participant was listed in 1 of the following 6 categories: 0, >0 to 0.5, >0.5 to 1, >1 to 2, >2 to 3, and >3 days per week.
Time Frame	Week 21 to Week 32
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.
Analysis performed using the Full Analysis Set (FAS) population which included all randomized participants that did not have a withdrawal visit and/or did not have at least 1 GFSS score during the post-withdrawal period (Weeks 21 to 32).

Reporting Groups

	Description
ERN/LRPT	One 1g/20 mg tablet ERN/LRPT once daily for 4 weeks, then two 1g/20 mg tablets daily (2g/40 mg total) for 28 weeks
ERN/LRPT Then ERN	One 1g/20mg tablet ERN/LRPT once daily for 4 weeks, then two 1g/20 mg tablets daily (2g/40 mg total) for 16 weeks then Two 1g tablets ERN (2g total) once daily for 12 weeks.
Placebo	One tablet placebo to ERN/LRPT once daily for 4 weeks, then two tablets placebo to ERN/LRPT daily for 28 weeks.

Measured Values

	ERN/LRPT	**ERN/LRPT Then ERN**	**Placebo**
Number of Participants Analyzed [units: participants]	**362**	**354**	**207**
Number Participants With Days Per Week With Global Flushing Severity Score (GFSS) ≥4 Partitioned Into 6			

Categories During the Postwithdrawal Period [units: Participants]			
0 Days per week	291	181	188
>0 to ≤ 0.5 Days per week	43	74	7
>0.5 to ≤1 Days per week	3	32	4
>1.0 to ≤2 Days per week	8	30	3
>2 to ≤3 Days per week	1	17	1
>3 Days per week	16	20	4

Statistical Analysis 1 for Number Participants With Days Per Week With Global Flushing Severity Score (GFSS) ≥4 Partitioned Into 6 Categories During the Postwithdrawal Period

Groups [1]	ERN/LRPT vs. ERN/LRPT Then ERN
Method [2]	Cochran-Mantel-Haenszel
P Value [3]	<0.001

[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:
	Cochran-Mantel-Haenszel (CMH) test was stratified by country
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	The closed ordered testing procedure was applied to the efficacy hypotheses. If statistical significance was achieved for the primary hypothesis, then the secondary hypothesis was tested. All tests were performed at significance level 0.05.

2. Secondary: Number of Participants With Maximum GFSS ≥4 During the Post-withdrawal Period [Time Frame: Week 21 to Week 32]

Measure Type	Secondary
Measure Title	Number of Participants With Maximum GFSS ≥4 During the Post-withdrawal Period
Measure Description	Flushing symptoms were recorded using participant's response to the Global Flushing Severity Score (GFSS), which assesses the overall severity of the flushing experience (including redness, warmth, tingling, or itching) using a scale with response categories of None, Mild, Moderate, Severe, and Extreme. The categories were supplemented with numbers 0 to 10 to allow for greater precision within each category (None=0, Mild=1-3, Moderate=4-6, Severe=7-9, Extreme=10). The daily response was recorded in the morning, and reflected the symptoms experienced during the previous 24 hours.
Time Frame	Week 21 to Week 32
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.
Analysis performed using the Full Analysis Set (FAS) population which included all randomized participants that did not have a withdrawal visit and/or did not have at least 1 GFSS score during the post-withdrawal period (Weeks 21 to 32).

Reporting Groups

	Description
ERN/LRPT	One 1g/20 mg tablet ERN/LRPT once daily for 4 weeks, then two 1g/20 mg tablets daily (2g/40 mg total) for 28 weeks
ERN/LRPT Then ERN	One 1g/20mg tablet ERN/LRPT once daily for 4 weeks, then two 1g/20 mg tablets daily (2g/40 mg total) for 16 weeks then Two 1g tablets ERN (2g total) once daily for 12 weeks.
Placebo	One tablet placebo to ERN/LRPT once daily for 4 weeks, then two tablets placebo to ERN/LRPT daily for 28 weeks.

Measured Values

	ERN/LRPT	ERN/LRPT Then ERN	Placebo
Number of Participants Analyzed [units: participants]	**362**	**354**	**207**
Number of Participants With Maximum GFSS ≥4 During the Post-withdrawal Period [units: Participants]	**71**	**173**	**19**

Statistical Analysis 1 for Number of Participants With Maximum GFSS ≥4 During the Post-withdrawal Period

Groups [1]	ERN/LRPT vs. ERN/LRPT Then ERN
Method [2]	Unconditional Miettinen and Nurminen
P Value [3]	<0.001

[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:
	The closed ordered testing procedure was applied to the efficacy hypotheses. If statistical significance was achieved for the primary hypothesis, then the secondary hypothesis was tested. All tests were performed at significance level 0.05.

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	No text entered.
Additional Description	Of 1152 randomized participants, 1148 participants took at least one dose of study medication and were included in the analyses of safety.

Reporting Groups

	Description
ERN/LRPT	One 1g/20 mg tablet ERN/LRPT once daily for 4 weeks, then two 1g/20 mg tablets daily (2g/40 mg total) for 28 weeks
ERN/LRPT Then ERN	One 1g/20mg tablet ERN/LRPT once daily for 4 weeks, then two 1g/20 mg tablets daily (2g/40 mg total) for 16 weeks

	then Two 1g tablets ERN (2g total) once daily for 12 weeks.
Placebo	One tablet placebo to ERN/LRPT once daily for 4 weeks, then two tablets placebo to ERN/LRPT daily for 28 weeks.

Serious Adverse Events

	ERN/LRPT	ERN/LRPT Then ERN	Placebo
Total, serious adverse events			
# participants affected / at risk	**17/461 (3.69%)**	**34/455 (7.47%)**	**13/232 (5.60%)**
Cardiac disorders			
Angina pectoris †			
# participants affected / at risk	**0/461 (0.00%)**	**1/455 (0.22%)**	**0/232 (0.00%)**
# events	**0**	**2**	**0**
Angina unstable †			
# participants affected / at risk	**0/461 (0.00%)**	**1/455 (0.22%)**	**0/232 (0.00%)**
# events	**0**	**1**	**0**
Atrial fibrillation †			
# participants affected / at risk	**0/461 (0.00%)**	**2/455 (0.44%)**	**0/232 (0.00%)**
# events	**0**	**2**	**0**
Cardiac failure †			
# participants affected / at risk	**0/461 (0.00%)**	**1/455 (0.22%)**	**0/232 (0.00%)**
# events	**0**	**2**	**0**
Cardiac failure congestive †			
# participants affected / at risk	**0/461 (0.00%)**	**1/455 (0.22%)**	**0/232 (0.00%)**
# events	**0**	**1**	**0**
Coronary artery disease †			
# participants affected / at risk	**0/461 (0.00%)**	**2/455 (0.44%)**	**0/232 (0.00%)**
# events	**0**	**2**	**0**
Myocardial infarction †			
# participants affected / at risk	**0/461 (0.00%)**	**0/455 (0.00%)**	**1/232 (0.43%)**
# events	**0**	**0**	**1**
Supraventricular tachycardia †			
# participants affected / at risk	**0/461 (0.00%)**	**1/455 (0.22%)**	**0/232 (0.00%)**
# events	**0**	**1**	**0**
Ventricular tachycardia †			
# participants affected / at risk	**0/461 (0.00%)**	**0/455 (0.00%)**	**1/232 (0.43%)**
# events	**0**	**0**	**1**
Ear and labyrinth disorders			
Cerumen impaction †			
# participants affected / at risk	**0/461 (0.00%)**	**0/455 (0.00%)**	**1/232 (0.43%)**
# events	**0**	**0**	**1**
Endocrine disorders			
Goitre †			
# participants affected / at risk	**1/461 (0.22%)**	**0/455 (0.00%)**	**0/232 (0.00%)**
# events	**1**	**0**	**0**

Eye disorders			
Optic ischaemic neuropathy †			
# participants affected / at risk	**0/461 (0.00%)**	**0/455 (0.00%)**	**1/232 (0.43%)**
# events	**0**	**0**	**1**
Gastrointestinal disorders			
Gastric ulcer haemorrhage †			
# participants affected / at risk	**0/461 (0.00%)**	**1/455 (0.22%)**	**0/232 (0.00%)**
# events	**0**	**1**	**0**
Haemorrhoids †			
# participants affected / at risk	**0/461 (0.00%)**	**0/455 (0.00%)**	**1/232 (0.43%)**
# events	**0**	**0**	**1**
General disorders			
Device malfunction †			
# participants affected / at risk	**0/461 (0.00%)**	**1/455 (0.22%)**	**0/232 (0.00%)**
# events	**0**	**1**	**0**
Non-cardiac chest pain †			
# participants affected / at risk	**0/461 (0.00%)**	**1/455 (0.22%)**	**1/232 (0.43%)**
# events	**0**	**1**	**1**
Hepatobiliary disorders			
Cholelithiasis †			
# participants affected / at risk	**1/461 (0.22%)**	**0/455 (0.00%)**	**0/232 (0.00%)**
# events	**1**	**0**	**0**
Immune system disorders			
Drug hypersensitivity †			
# participants affected / at risk	**1/461 (0.22%)**	**0/455 (0.00%)**	**0/232 (0.00%)**
# events	**1**	**0**	**0**
Infections and infestations			
Cellulitis †			
# participants affected / at risk	**0/461 (0.00%)**	**0/455 (0.00%)**	**1/232 (0.43%)**
# events	**0**	**0**	**1**
Diverticulitis †			
# participants affected / at risk	**0/461 (0.00%)**	**1/455 (0.22%)**	**0/232 (0.00%)**
# events	**0**	**1**	**0**
H1N1 influenza †			
# participants affected / at risk	**1/461 (0.22%)**	**0/455 (0.00%)**	**0/232 (0.00%)**
# events	**1**	**0**	**0**
Pneumonia †			
# participants affected / at risk	**0/461 (0.00%)**	**1/455 (0.22%)**	**1/232 (0.43%)**
# events	**0**	**1**	**1**
Post procedural infection †			
# participants affected / at risk	**1/461 (0.22%)**	**0/455 (0.00%)**	**0/232 (0.00%)**
# events	**1**	**0**	**0**
Post procedural sepsis †			
# participants affected / at risk	**0/461 (0.00%)**	**1/455 (0.22%)**	**0/232 (0.00%)**

# events	0	1	0
Pyelonephritis †			
# participants affected / at risk	0/461 (0.00%)	0/455 (0.00%)	1/232 (0.43%)
# events	0	0	1
Urosepsis †			
# participants affected / at risk	1/461 (0.22%)	1/455 (0.22%)	0/232 (0.00%)
# events	1	1	0
Injury, poisoning and procedural complications			
Clavicle fracture †			
# participants affected / at risk	0/461 (0.00%)	1/455 (0.22%)	0/232 (0.00%)
# events	0	1	0
Concussion †			
# participants affected / at risk	0/461 (0.00%)	1/455 (0.22%)	1/232 (0.43%)
# events	0	1	1
Foreign body †			
# participants affected / at risk	0/461 (0.00%)	1/455 (0.22%)	0/232 (0.00%)
# events	0	1	0
Humerus fracture †			
# participants affected / at risk	0/461 (0.00%)	0/455 (0.00%)	1/232 (0.43%)
# events	0	0	1
Joint injury †			
# participants affected / at risk	0/461 (0.00%)	1/455 (0.22%)	0/232 (0.00%)
# events	0	1	0
Limb injury †			
# participants affected / at risk	0/461 (0.00%)	0/455 (0.00%)	1/232 (0.43%)
# events	0	0	1
Post procedural haematoma †			
# participants affected / at risk	0/461 (0.00%)	1/455 (0.22%)	0/232 (0.00%)
# events	0	1	0
Tendon rupture †			
# participants affected / at risk	1/461 (0.22%)	0/455 (0.00%)	0/232 (0.00%)
# events	1	0	0
Traumatic brain injury †			
# participants affected / at risk	0/461 (0.00%)	1/455 (0.22%)	0/232 (0.00%)
# events	0	1	0
Metabolism and nutrition disorders			
Hypokalaemia †			
# participants affected / at risk	1/461 (0.22%)	0/455 (0.00%)	0/232 (0.00%)
# events	1	0	0
Musculoskeletal and connective tissue disorders			
Back pain †			
# participants affected / at risk	0/461 (0.00%)	0/455 (0.00%)	1/232 (0.43%)
# events	0	0	1
Intervertebral disc protrusion †			
# participants affected / at risk	2/461 (0.43%)	0/455 (0.00%)	0/232 (0.00%)

# events	2	0	0
Musculoskeletal pain †			
# participants affected / at risk	0/461 (0.00%)	1/455 (0.22%)	0/232 (0.00%)
# events	0	1	0
Tendon disorder †			
# participants affected / at risk	1/461 (0.22%)	0/455 (0.00%)	0/232 (0.00%)
# events	1	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Breast cancer †			
# participants affected / at risk	0/461 (0.00%)	1/455 (0.22%)	0/232 (0.00%)
# events	0	1	0
Intraocular melanoma †			
# participants affected / at risk	0/461 (0.00%)	1/455 (0.22%)	0/232 (0.00%)
# events	0	1	0
Prostate cancer †			
# participants affected / at risk	2/461 (0.43%)	2/455 (0.44%)	0/232 (0.00%)
# events	2	2	0
Tongue cancer metastatic †			
# participants affected / at risk	0/461 (0.00%)	1/455 (0.22%)	0/232 (0.00%)
# events	0	1	0
Nervous system disorders			
Cerebral haemorrhage †			
# participants affected / at risk	0/461 (0.00%)	1/455 (0.22%)	0/232 (0.00%)
# events	0	1	0
Epileptic aura †			
# participants affected / at risk	1/461 (0.22%)	0/455 (0.00%)	0/232 (0.00%)
# events	1	0	0
Haemorrhage intracranial †			
# participants affected / at risk	0/461 (0.00%)	0/455 (0.00%)	1/232 (0.43%)
# events	0	0	1
Headache †			
# participants affected / at risk	0/461 (0.00%)	1/455 (0.22%)	0/232 (0.00%)
# events	0	1	0
Syncope †			
# participants affected / at risk	0/461 (0.00%)	1/455 (0.22%)	0/232 (0.00%)
# events	0	1	0
Transient ischaemic attack †			
# participants affected / at risk	0/461 (0.00%)	1/455 (0.22%)	0/232 (0.00%)
# events	0	1	0
Psychiatric disorders			
Alcoholism †			
# participants affected / at risk	0/461 (0.00%)	1/455 (0.22%)	0/232 (0.00%)
# events	0	1	0
Major depression †			

# participants affected / at risk	1/461 (0.22%)	0/455 (0.00%)	0/232 (0.00%)
# events	1	0	0
Renal and urinary disorders			
Nephrolithiasis †			
# participants affected / at risk	0/461 (0.00%)	1/455 (0.22%)	0/232 (0.00%)
# events	0	1	0
Urinary incontinence †			
# participants affected / at risk	1/461 (0.22%)	0/455 (0.00%)	0/232 (0.00%)
# events	1	0	0
Respiratory, thoracic and mediastinal disorders			
Acute pulmonary oedema †			
# participants affected / at risk	0/461 (0.00%)	0/455 (0.00%)	1/232 (0.43%)
# events	0	0	1
Pulmonary embolism †			
# participants affected / at risk	1/461 (0.22%)	1/455 (0.22%)	0/232 (0.00%)
# events	1	1	0
Skin and subcutaneous tissue disorders			
Drug eruption †			
# participants affected / at risk	0/461 (0.00%)	1/455 (0.22%)	0/232 (0.00%)
# events	0	1	0
Vascular disorders			
Arteriosclerosis †			
# participants affected / at risk	0/461 (0.00%)	0/455 (0.00%)	1/232 (0.43%)
# events	0	0	1
Thrombophlebitis †			
# participants affected / at risk	0/461 (0.00%)	1/455 (0.22%)	0/232 (0.00%)
# events	0	1	0
Thrombophlebitis superficial †			
# participants affected / at risk	0/461 (0.00%)	1/455 (0.22%)	0/232 (0.00%)
# events	0	1	0

† Events were collected by systematic assessment

Other Adverse Events

Hide Other Adverse Events

Time Frame	No text entered.
Additional Description	Of 1152 randomized participants, 1148 participants took at least one dose of study medication and were included in the analyses of safety.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
ERN/LRPT	One 1g/20 mg tablet ERN/LRPT once daily for 4 weeks, then two 1g/20 mg tablets daily (2g/40 mg total) for 28 weeks
ERN/LRPT Then ERN	One 1g/20mg tablet ERN/LRPT once daily for 4 weeks, then two 1g/20 mg tablets daily (2g/40 mg total) for 16 weeks then Two 1g tablets ERN (2g total) once daily for 12 weeks.
Placebo	One tablet placebo to ERN/LRPT once daily for 4 weeks, then two tablets placebo to ERN/LRPT daily for 28 weeks.

Other Adverse Events

	ERN/LRPT	ERN/LRPT Then ERN	Placebo
Total, other (not including serious) adverse events			
# participants affected / at risk	**136/461 (29.50%)**	**162/455 (35.60%)**	**37/232 (15.95%)**
Infections and infestations			
Nasopharyngitis †			
# participants affected / at risk	**33/461 (7.16%)**	**34/455 (7.47%)**	**11/232 (4.74%)**
# events	**40**	**35**	**12**
Nervous system disorders			
Paraesthesia †			
# participants affected / at risk	**23/461 (4.99%)**	**28/455 (6.15%)**	**6/232 (2.59%)**
# events	**53**	**65**	**6**
Skin and subcutaneous tissue disorders			
Pruritis †			
# participants affected / at risk	**51/461 (11.06%)**	**66/455 (14.51%)**	**17/232 (7.33%)**
# events	**67**	**116**	**18**
Vascular disorders			
Flushing †			
# participants affected / at risk	**52/461 (11.28%)**	**85/455 (18.68%)**	**7/232 (3.02%)**
# events	**77**	**130**	**7**

† Events were collected by systematic assessment

Limitations and Caveats

Hide Limitations and Caveats

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

More Information

Hide More Information

Certain Agreements:

Principal Investigators are **NOT** employed by the organization sponsoring the study.
There **IS** an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial

results after the trial is completed.

The agreement is:

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

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

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

☑ **Restriction Description:** Publications derived from this study should include input from the investigator(s) and Sponsor personnel. Subsequent to the multicenter publication, or 24 months after completion of the study, whichever comes first, an investigator and/or his/her colleagues may publish the results for their study site independently. The Sponsor must have the opportunity to review all proposed abstracts, manuscripts, or presentations regarding this study 60 days prior to submission for publication/presentation.

Results Point of Contact:

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

Publications of Results:

Maccubbin DL, Chen F, Anderson JW, Sirah W, McCrary Sisk C, Kher U, Olsson AG, Bays HE, Mitchel YB. Effectiveness and safety of laropiprant on niacin-induced flushing. Am J Cardiol. 2012 Sep 15;110(6):817-22. doi: 10.1016/j.amjcard.2012.05.009. Epub 2012 Jun 8.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00961636 History of Changes
Other Study ID Numbers:	0524A-102 2009_634
Study First Received:	August 17, 2009
Results First Received:	January 14, 2012
Last Updated:	January 29, 2015
Health Authority:	United States: Food and Drug Administration

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