Efficacy and Safety of Extended Release (ER) Niacin/Laropiprant When Added to Ongoing Lipid-Modifying Therapy in Patients With High Cholesterol or Abnormal Lipid Levels (MK-0524A-133)

This study has been terminated.

(In HPS2-THRIVE, MK-0524A did not meet the primary efficacy objective and there was a significant increase in incidence of some types of non-fatal SAEs)

Sponsor:
Merck Sharp & Dohme Corp.

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

ClinicalTrials.gov Identifier:
NCT01274559

First received: October 25, 2010
Last updated: April 27, 2015
Last verified: April 2015
History of Changes

Purpose

This is a multicenter, randomized, double-blind, placebo-controlled study in participants with primary hypercholesterolemia or mixed dyslipidemia, and elevated low density lipoprotein-cholesterol (LDL-C) to assess the efficacy and safety of extended release (ER) niacin/laropiprant [ERN/LRPT (MK-0524A)] when added to the following ongoing lipid-modifying therapy (LMT): simvastatin,

atorvastatin, rosuvastatin monotherapy, ezetimibe/simvastatin fixed dose combination (FDC), or any statin co-administered with ezetimibe. The study is based on the hypothesis that ERN/LRPT 2 g daily will be superior to placebo at lowering LDL-C at Week 12 of treatment.

Condition	Intervention	Phase
Primary Hypercholesterolemia Mixed Dyslipidemia	Drug: Extended-release niacin/laropiprant (ERN/LRPT) Drug: Placebo	Phase 3

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: 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 12-Week Study to Evaluate the Efficacy and Safety of Extended Release (ER) Niacin/Laropiprant When Added to Ongoing Lipid-Modifying Therapy in Patients With Primary Hypercholesterolemia or Mixed Dyslipidemia

Resource links provided by NLM:

MedlinePlus related topics: Cholesterol

Drug Information available for: Niacin Niacinamide

U.S. FDA Resources

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

Primary Outcome Measures:

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

Secondary Outcome Measures:

- Percent Change From Baseline in LDL-C:High-density Lipoprotein Cholesterol (HDL-C) at Week 12 [Time Frame: Baseline and Week 12] [Designated as safety issue: No]
- Percent Change From Baseline in HDL-C at Week 12 [Time Frame: Baseline and Week 12] [Designated as safety issue: No]
- Percent Change From Baseline in Triglyceride (TG) at Week 12 [Time Frame: Baseline and Week 12] [Designated as safety issue: No]
- Percent Change From Baseline in Non-HDL-C at Week 12 [Time Frame: Baseline and Week 12] [Designated as safety issue: No]
- Percent Change From Baseline in Apolipoprotein B (Apo B) at Week 12 [Time Frame: Baseline and Week 12] [Designated as safety issue: No]
- Percent Change From Baseline in Apo B:Apolipoprotein A-I (Apo A-I) at Week 12 [Time Frame: Baseline and Week 12] [Designated as safety issue: No]
- Percent Change From Baseline in Total Cholesterol (TC):HDL-C at Week 12 [Time Frame: Baseline and Week 12] [Designated as safety issue: No]
- Percent Change From Baseline in Lipoprotein a [Lp(a)] at Week 12 [Time Frame: Baseline and Week 12] [Designated as safety issue: No]
- Percent Change From Baseline in Apo A-I at Week 12 [Time Frame: Baseline and Week 12] [Designated as safety issue: No]
- Percent Change From Baseline in TC at Week 12 [Time Frame: Baseline and Week 12] [Designated as safety issue: No]
- Percent Change From Baseline in LDL-C at Week 4 [Time Frame: Baseline and Week 4] [Designated as safety issue: No]
- Percent Change From Baseline in LDL-C:HDL-C at Week 4 [Time Frame: Baseline and Week 4] [Designated as safety issue: No]
- Percent Change From Baseline in HDL-C at Week 4 [Time Frame: Baseline and Week 4] [Designated as safety issue: No]
- Percent Change From Baseline in TG at Week 4 [Time Frame: Baseline and Week 4] [Designated as safety issue: No]
- Percent Change From Baseline in Non-HDL-C at Week 4 [Time Frame: Baseline and Week 4] [Designated as safety issue: No]
- Percent Change From Baseline in Apo B at Week 4 [Time Frame: Baseline and Week 4] [Designated as safety issue: No]
- Percent Change From Baseline in Apo B:Apo A-I at Week 4 [Time Frame: Baseline and Week 4] [Designated as safety issue: No]
- Percent Change From Baseline in TC:HDL-C at Week 4 [Time Frame: Baseline and Week 4] [Designated as safety issue: No]
- Percent Change From Baseline in Lp(a) at Week 4 [Time Frame: Baseline and Week 4] [Designated as safety issue: No]
- Percent Change From Baseline in Apo A-I at Week 4 [Time Frame: Baseline and Week 4] [Designated as safety issue: No]
- Percent Change From Baseline in TC at Week 4 [Time Frame: Baseline and Week 4] [Designated as safety issue: No]
- Number of Participants Who Achieve LDL-C Target Levels at Week 12 of Treatment [Time Frame: Baseline and 12 weeks] [Designated as safety issue: No]

  assessed as per National Cholesterol Education Program (NCEP) Adult Treatment Panel III (ATP III) and European Society of Cardiology (ESC) treatment guidelines

Enrollment:	1173
Study Start Date:	March 2011
Study Completion Date:	February 2013
Primary Completion Date:	February 2013 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: Extended-release niacin/laropiprant ERN/LRPT 1 g (1 tablet for 4 wks) followed by ERN/LRPT 2 g (2 tablets for 8 wks); Each 1-g tablet contains 1 g of ER niacin and 20 mg of laropiprant.	Drug: Extended-release niacin/laropiprant (ERN/LRPT) 1 oral 1 g tablet of ERN/LRPT to be taken with food in the evening or at bedtime for the first 4 weeks of treatment; then 2 oral 1g tablets of ERN/LRPT to be taken together in the evening or at bedtime with food for the next 8 weeks. Each 1g tablet contains 1g ERN and 20 mg LRPT

Placebo Comparator: Placebo Matching 1 g Placebo (1 tablet for 4 wks) followed by 2 g placebo (2 tablets for 8 weeks)	Drug: Placebo 1 oral 1 g tablet of placebo to be taken with food in the evening or at bedtime for the first 4 weeks of treatment; then 2 oral 1g tablets of placebo to be taken together in the evening or at bedtime with food for the next 8 weeks.

Eligibility

Ages Eligible for Study: 18 Years and older
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- Has a history of primary hypercholesterolemia or mixed dyslipidemia.
- Must meet one of the risk categories (very high, high or moderate and corresponding LDL-C criteria at Visit 2.
- Has TG levels <500 mg/dL (<5.65 mmol/L).
- Has been on a stable dose of one of the following lipid-modifying therapies (LMTs)for at least 6 weeks prior to Visit 1, and agrees to remain on the same type and dose of LMT for the duration of the study:
  - Monotherapy: any statin
  - Combination Therapy: ezetimibe/simvastatin in the same tablet
  - Co-administration Therapy: any statin co-administered with ezetimibe
- Is male or female and ≥18 years of age on day of signing informed consent.
- A female must meet ONE of the following:
  - Of reproductive potential and agrees to remain abstinent or use (or have their partner use) 2 acceptable methods of birth control for the study duration.
  - Not of reproductive potential is eligible without requiring the use of contraception. Definition of "not of reproductive potential": one who has either of the following:
    - reached natural menopause, defined as: 6 months of spontaneous amenorrhea with serum FSH levels (at Visit 1) in the postmenopausal range (per central lab) or 12 months of spontaneous amenorrhea.Spontaneous amenorrhea does not include cases for which there is an underlying disease that causes amenorrhea (e.g., anorexia nervosa).
    - 6 weeks post surgical hysterectomy, or bilateral oophorectomy with or without hysterectomy.
    - Bilateral tubal ligation without subsequent restorative procedure.
- Understands the study's procedures, alternative treatments available, risks involved with the study, and voluntarily agrees to participate by giving written informed consent.

Exclusion Criteria

- Has taken a prohibited LMT within 6 weeks of Visit 1. Examples of

prohibited LMT include bile acid sequestrants, fibrates (monotherapy, coadministration or combination with other LMT), niacin >50 mg, and red yeast rice products.

- Has had a change to the type or dose of acceptable LMT regimen within 6 weeks of Visit 1.
- Is pregnant, breastfeeding, or expecting to conceive during the study including the 14-day poststudy follow-up.
- Has a history of malignancy ≤5 years prior to signing informed consent, except for adequately treated basal cell or squamous cell skin cancer or in situ cervical cancer.
- Female who is expecting to donate eggs during the study, including the 14-day follow-up.
- Is unlikely to adhere to the study procedures, keep appointments, or is planning to relocate during the study.
- Has participated in a study, including post-study follow-up, with an investigational compound (non-lipid-modifying) within 30 days of Visit 1 or a lipid-modifying compound (investigational or marketed), within 6 weeks of Visit 1.
- Has donated and/or received blood as follows:
  - donated blood products or has had phlebotomy of >300 mL within 8 weeks prior to signing informed consent.
  - intends to give or receive blood products during the study.
  - intends to donate more than 250 mL of blood products within 8 weeks following the last study visit.
- Has the following exclusionary laboratory values at Visit 2
  - Creatinine clearance (eGFR) <30 mL/min (0.50 mL/s)

- ALT (SGPT) >1.5 x ULN
- AST (SGOT) >1.5 x ULN
- CK >2 x ULN

- Has used recreational or illicit drugs within 1 year of signing informed consent.
- Was <80% compliant with LMT or placebo at Visit 2, AND in the opinion of the investigator, is believed to be unable to maintain at least 80% compliance with dosing during the active treatment period.
- Has chronic heart failure defined by the New York Heart Association (NYHA) Classes III or IV, uncontrolled cardiac arrhythmias, or poorly controlled hypertension (systolic blood pressure >160 mm Hg or diastolic >100 mm Hg).
- Has Type 1 or Type 2 diabetes mellitus and meets one or more of the following criteria:
  - Is poorly controlled (HbA1C >8.0% at Visit 1)
  - Is newly diagnosed (within 3 months of Visit 1)
  - Has recently experienced repeated hypoglycemia or unstable glycemic control (within 3 months of Visit 1).
  - Is taking new or recently adjusted antidiabetic pharmacotherapy (with the exception of ± ≤ 10 units of insulin) within 3 months of Visit 1.
- Has uncontrolled endocrine or metabolic disease known to influence serum lipids or lipoproteins (i.e., secondary causes of hyperlipidemia such as hyper- or hypothyroidism.
- Has nephrotic syndrome or other clinically significant renal disease.
- Has active peptic ulcer disease within 3 months of Visit 1.
- Has a history of hypersensitivity or allergic reaction to niacin or niacin containing products.
- Has history of myocardial infarction, stroke, coronary artery bypass surgery or other revascularization procedure, unstable angina or angioplasty within 3 months of Visit 1.
- Has arterial bleeding.
- Has a history of ileal bypass, gastric bypass or other significant condition associated with malabsorption or rapid weight loss within 18 months of Visit 1.
- Has active or chronic hepatobiliary or hepatic disease.
- Is Chinese and is on simvastatin 80 mg or a product containing simvastatin 80 mg at Visit 1.
- Is receiving treatment with systemic steroids (intravenous, injected, and oral steroids) OR systemic anabolic agents.
- Consumes more than 3 alcoholic drinks on any given day or more than 14 drinks per week.
- Is taking the following antioxidant vitamins each day:
  - Vitamin C in excess of 1500 mg
  - Vitamin E in excess of 45 IU for men, 36 IU for women
  - Beta Carotene 15000 IU for men, 12000 IU for women

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.

No Contacts or Locations Provided

More Information

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT01274559 History of Changes
Other Study ID Numbers:	0524A-133 CTRI/2012/08/002857
Study First Received:	October 25, 2010
Results First Received:	January 30, 2014
Last Updated:	April 27, 2015
Health Authority:	United States: Food and Drug Administration

Keywords provided by Merck Sharp & Dohme Corp.:
MK-0524A/ER
Hypercholesterolemia
Dyslipidemia
Niacin

Laropiprant

Additional relevant MeSH terms:

Dyslipidemias
Hypercholesterolemia
Hyperlipidemias
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

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This study has been terminated.

(In HPS2-THRIVE, MK-0524A did not meet the primary efficacy objective and there was a significant increase in incidence of some types of non-fatal SAEs)

Sponsor:
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ClinicalTrials.gov Identifier:
NCT01274559

First received: October 25, 2010
Last updated: April 27, 2015
Last verified: April 2015
History of Changes

Results First Received: January 30, 2014

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Investigator); Primary Purpose: Treatment
Conditions:	Primary Hypercholesterolemia Mixed Dyslipidemia
Interventions:	Drug: Extended-release niacin/laropiprant (ERN/LRPT) Drug: Placebo

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
Phase 3 study HPS2-THRIVE (NCT00461630) did not meet its primary endpoint of reduction of major vascular events and had a significant

increase in the incidence of some types of non-fatal serious adverse events. As a result, MK-0524A-133 was discontinued. Only individual data were obtained; none of the planned efficacy outcomes were summarized.

Reporting Groups

	Description
Extended-release Niacin/Laropiprant	Extended-release niacin (ERN)/laropiprant (LRPT) 1 g (1 tablet for 4 wks) followed by ERN/LRPT 2 g (2 tablets for 8 wks); Each 1-g tablet contains 1 g of ER niacin and 20 mg of laropiprant.
Placebo	Matching 1 g Placebo (1 tablet for 4 wks) followed by 2 g placebo (2 tablets for 8 weeks)

Participant Flow: Overall Study

	Extended-release Niacin/Laropiprant	Placebo
STARTED	**587**	**586**
Treated	**572**	**572**
COMPLETED	**390**	**441**
NOT COMPLETED	**197**	**145**
Adverse Event	**57**	**13**
Death	**1**	**1**
Lost to Follow-up	**3**	**3**
Non-compliance with Study Drug	**2**	**4**
Physician Decision	**2**	**1**
Protocol Violation	**28**	**23**
Study Terminated by Sponsor	**79**	**87**
Withdrawal by Subject	**25**	**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
Extended-release Niacin/Laropiprant	ERN/LRPT 1 g (1 tablet for 4 wks) followed by ERN/LRPT 2 g (2 tablets for 8 wks); Each 1-g tablet contains 1 g of ER niacin and 20 mg of laropiprant.
Placebo	Matching 1 g Placebo (1 tablet for 4 wks) followed by 2 g placebo (2 tablets for 8 weeks)
Total	Total of all reporting groups

Baseline Measures

	Extended-release Niacin/Laropiprant	Placebo	Total
Number of Participants [units: participants]	587	586	1173
Age, Customized [units: Participants]			
21 to 30 years	1	2	3
31 to 40 years	9	12	21
41 to 50 years	63	62	125
51 to 60 years	182	168	350
61 to 70 years	209	232	441
71 to 80 years	108	98	206
>80 years	15	12	27
Gender [units: Participants]			
Female	239	243	482
Male	348	343	691

Outcome Measures

Hide All Outcome Measures

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

Measure Type	Primary
Measure Title	Percent Change From Baseline at Week 12 in Low Density Lipoprotein-Cholesterol (LDL-C)
Measure Description	No text entered.
Time Frame	Baseline and Week 12
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.
Study was terminated. Efficacy endpoints were not summarized and no planned efficacy analyses were performed.

Reporting Groups

	Description
Extended-release Niacin/Laropiprant	ERN/LRPT 1 g (1 tablet for 4 wks) followed by ERN/LRPT 2 g (2 tablets for 8 wks); Each 1-g tablet contains 1 g of ER niacin and 20 mg of laropiprant.
Placebo	Matching 1 g Placebo (1 tablet for 4 wks) followed by 2 g placebo (2 tablets for 8 weeks)

Measured Values

	Extended-release Niacin/Laropiprant	Placebo
Number of Participants Analyzed [units: participants]	**0**	**0**
Percent Change From Baseline at Week 12 in Low Density Lipoprotein-Cholesterol (LDL-C)		

No statistical analysis provided for Percent Change From Baseline at Week 12 in Low Density Lipoprotein-Cholesterol (LDL-C)

2. Secondary: Percent Change From Baseline in LDL-C:High-density Lipoprotein Cholesterol (HDL-C) at Week 12 [Time Frame: Baseline and Week 12]

Measure Type	Secondary
Measure Title	Percent Change From Baseline in LDL-C:High-density Lipoprotein Cholesterol (HDL-C) at Week 12
Measure Description	No text entered.
Time Frame	Baseline and Week 12
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.
Study was terminated. Efficacy endpoints were not summarized and no planned efficacy analyses were performed.

Reporting Groups

	Description
Extended-release Niacin/Laropiprant	ERN/LRPT 1 g (1 tablet for 4 wks) followed by ERN/LRPT 2 g (2 tablets for 8 wks); Each 1-g tablet contains 1 g of ER niacin and 20 mg of laropiprant.
Placebo	Matching 1 g Placebo (1 tablet for 4 wks) followed by 2 g placebo (2 tablets for 8 weeks)

Measured Values

	Extended-release Niacin/Laropiprant	Placebo
Number of Participants Analyzed [units: participants]	**0**	**0**
Percent Change From Baseline in LDL-C:High-density Lipoprotein Cholesterol (HDL-C) at Week 12		

No statistical analysis provided for Percent Change From Baseline in LDL-C:High-density Lipoprotein Cholesterol (HDL-C) at Week 12

3. Secondary: Percent Change From Baseline in HDL-C at Week 12 [Time Frame: Baseline and Week 12]

Measure Type	Secondary
Measure Title	Percent Change From Baseline in HDL-C at Week 12

Measure Description	No text entered.
Time Frame	Baseline and Week 12
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.
Study was terminated. Efficacy endpoints were not summarized and no planned efficacy analyses were performed.

Reporting Groups

	Description
Extended-release Niacin/Laropiprant	ERN/LRPT 1 g (1 tablet for 4 wks) followed by ERN/LRPT 2 g (2 tablets for 8 wks); Each 1-g tablet contains 1 g of ER niacin and 20 mg of laropiprant.
Placebo	Matching 1 g Placebo (1 tablet for 4 wks) followed by 2 g placebo (2 tablets for 8 weeks)

Measured Values

	Extended-release Niacin/Laropiprant	**Placebo**
Number of Participants Analyzed [units: participants]	**0**	**0**
Percent Change From Baseline in HDL-C at Week 12		

No statistical analysis provided for Percent Change From Baseline in HDL-C at Week 12

4. Secondary: Percent Change From Baseline in Triglyceride (TG) at Week 12 [Time Frame: Baseline and Week 12]

Measure Type	Secondary
Measure Title	Percent Change From Baseline in Triglyceride (TG) at Week 12
Measure Description	No text entered.
Time Frame	Baseline and Week 12
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.
Study was terminated. Efficacy endpoints were not summarized and no planned efficacy analyses were performed.

Reporting Groups

	Description
Extended-release Niacin/Laropiprant	ERN/LRPT 1 g (1 tablet for 4 wks) followed by ERN/LRPT 2 g (2 tablets for 8 wks); Each 1-g tablet contains 1 g of ER niacin and 20 mg of laropiprant.
Placebo	Matching 1 g Placebo (1 tablet for 4 wks) followed by 2 g placebo (2 tablets for 8 weeks)

Measured Values

	Extended-release Niacin/Laropiprant	Placebo
Number of Participants Analyzed [units: participants]	**0**	**0**
Percent Change From Baseline in Triglyceride (TG) at Week 12		

No statistical analysis provided for Percent Change From Baseline in Triglyceride (TG) at Week 12

5. Secondary: Percent Change From Baseline in Non-HDL-C at Week 12 [Time Frame: Baseline and Week 12]

Measure Type	Secondary
Measure Title	Percent Change From Baseline in Non-HDL-C at Week 12
Measure Description	No text entered.
Time Frame	Baseline and Week 12
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.
Study was terminated. Efficacy endpoints were not summarized and no planned efficacy analyses were performed.

Reporting Groups

	Description
Extended-release Niacin/Laropiprant	ERN/LRPT 1 g (1 tablet for 4 wks) followed by ERN/LRPT 2 g (2 tablets for 8 wks); Each 1-g tablet contains 1 g of ER niacin and 20 mg of laropiprant.
Placebo	Matching 1 g Placebo (1 tablet for 4 wks) followed by 2 g placebo (2 tablets for 8 weeks)

Measured Values

	Extended-release Niacin/Laropiprant	Placebo
Number of Participants Analyzed [units: participants]	**0**	**0**
Percent Change From Baseline in Non-HDL-C at Week 12		

No statistical analysis provided for Percent Change From Baseline in Non-HDL-C at Week 12

6. Secondary: Percent Change From Baseline in Apolipoprotein B (Apo B) at Week 12 [Time Frame: Baseline and Week 12]

Measure Type	Secondary
Measure Title	Percent Change From Baseline in Apolipoprotein B (Apo B) at Week 12
Measure Description	No text entered.

Time Frame	Baseline and Week 12
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.
Study was terminated. Efficacy endpoints were not summarized and no planned efficacy analyses were performed.

Reporting Groups

	Description
Extended-release Niacin/Laropiprant	ERN/LRPT 1 g (1 tablet for 4 wks) followed by ERN/LRPT 2 g (2 tablets for 8 wks); Each 1-g tablet contains 1 g of ER niacin and 20 mg of laropiprant.
Placebo	Matching 1 g Placebo (1 tablet for 4 wks) followed by 2 g placebo (2 tablets for 8 weeks)

Measured Values

	Extended-release Niacin/Laropiprant	**Placebo**
Number of Participants Analyzed [units: participants]	**0**	**0**
Percent Change From Baseline in Apolipoprotein B (Apo B) at Week 12		

No statistical analysis provided for Percent Change From Baseline in Apolipoprotein B (Apo B) at Week 12

7. Secondary: Percent Change From Baseline in Apo B:Apolipoprotein A-I (Apo A-I) at Week 12 [Time Frame: Baseline and Week 12]

Measure Type	Secondary
Measure Title	Percent Change From Baseline in Apo B:Apolipoprotein A-I (Apo A-I) at Week 12
Measure Description	No text entered.
Time Frame	Baseline and Week 12
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.
Study was terminated. Efficacy endpoints were not summarized and no planned efficacy analyses were performed.

Reporting Groups

	Description
Extended-release Niacin/Laropiprant	ERN/LRPT 1 g (1 tablet for 4 wks) followed by ERN/LRPT 2 g (2 tablets for 8 wks); Each 1-g tablet contains 1 g of ER niacin and 20 mg of laropiprant.
Placebo	Matching 1 g Placebo (1 tablet for 4 wks) followed by 2 g placebo (2 tablets for 8 weeks)

Measured Values

	Extended-release Niacin/Laropiprant	Placebo
Number of Participants Analyzed [units: participants]	**0**	**0**
Percent Change From Baseline in Apo B:Apolipoprotein A-I (Apo A-I) at Week 12		

No statistical analysis provided for Percent Change From Baseline in Apo B:Apolipoprotein A-I (Apo A-I) at Week 12

8. Secondary: Percent Change From Baseline in Total Cholesterol (TC):HDL-C at Week 12 [Time Frame: Baseline and Week 12]

Measure Type	Secondary
Measure Title	Percent Change From Baseline in Total Cholesterol (TC):HDL-C at Week 12
Measure Description	No text entered.
Time Frame	Baseline and Week 12
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.
Study was terminated. Efficacy endpoints were not summarized and no planned efficacy analyses were performed.

Reporting Groups

	Description
Extended-release Niacin/Laropiprant	ERN/LRPT 1 g (1 tablet for 4 wks) followed by ERN/LRPT 2 g (2 tablets for 8 wks); Each 1-g tablet contains 1 g of ER niacin and 20 mg of laropiprant.
Placebo	Matching 1 g Placebo (1 tablet for 4 wks) followed by 2 g placebo (2 tablets for 8 weeks)

Measured Values

	Extended-release Niacin/Laropiprant	Placebo
Number of Participants Analyzed [units: participants]	**0**	**0**
Percent Change From Baseline in Total Cholesterol (TC):HDL-C at Week 12		

No statistical analysis provided for Percent Change From Baseline in Total Cholesterol (TC):HDL-C at Week 12

9. Secondary: Percent Change From Baseline in Lipoprotein a [Lp(a)] at Week 12 [Time Frame: Baseline and Week 12]

Measure Type	Secondary
Measure Title	Percent Change From Baseline in Lipoprotein a [Lp(a)] at Week 12
Measure Description	No text entered.

Time Frame	Baseline and Week 12
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.
Study was terminated. Efficacy endpoints were not summarized and no planned efficacy analyses were performed.

Reporting Groups

	Description
Extended-release Niacin/Laropiprant	ERN/LRPT 1 g (1 tablet for 4 wks) followed by ERN/LRPT 2 g (2 tablets for 8 wks); Each 1-g tablet contains 1 g of ER niacin and 20 mg of laropiprant.
Placebo	Matching 1 g Placebo (1 tablet for 4 wks) followed by 2 g placebo (2 tablets for 8 weeks)

Measured Values

	Extended-release Niacin/Laropiprant	**Placebo**
Number of Participants Analyzed [units: participants]	**0**	**0**
Percent Change From Baseline in Lipoprotein a [Lp(a)] at Week 12		

No statistical analysis provided for Percent Change From Baseline in Lipoprotein a [Lp(a)] at Week 12

10. Secondary: Percent Change From Baseline in Apo A-I at Week 12 [Time Frame: Baseline and Week 12]

Measure Type	Secondary
Measure Title	Percent Change From Baseline in Apo A-I at Week 12
Measure Description	No text entered.
Time Frame	Baseline and Week 12
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.
Study was terminated. Efficacy endpoints were not summarized and no planned efficacy analyses were performed.

Reporting Groups

	Description
Extended-release Niacin/Laropiprant	ERN/LRPT 1 g (1 tablet for 4 wks) followed by ERN/LRPT 2 g (2 tablets for 8 wks); Each 1-g tablet contains 1 g of ER niacin and 20 mg of laropiprant.
Placebo	Matching 1 g Placebo (1 tablet for 4 wks) followed by 2 g placebo (2 tablets for 8 weeks)

Measured Values

	Extended-release Niacin/Laropiprant	Placebo
Number of Participants Analyzed [units: participants]	**0**	**0**
Percent Change From Baseline in Apo A-I at Week 12		

No statistical analysis provided for Percent Change From Baseline in Apo A-I at Week 12

11. Secondary: Percent Change From Baseline in TC at Week 12 [Time Frame: Baseline and Week 12]

Measure Type	Secondary
Measure Title	Percent Change From Baseline in TC at Week 12
Measure Description	No text entered.
Time Frame	Baseline and Week 12
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.
Study was terminated. Efficacy endpoints were not summarized and no planned efficacy analyses were performed.

Reporting Groups

	Description
Extended-release Niacin/Laropiprant	ERN/LRPT 1 g (1 tablet for 4 wks) followed by ERN/LRPT 2 g (2 tablets for 8 wks); Each 1-g tablet contains 1 g of ER niacin and 20 mg of laropiprant.
Placebo	Matching 1 g Placebo (1 tablet for 4 wks) followed by 2 g placebo (2 tablets for 8 weeks)

Measured Values

	Extended-release Niacin/Laropiprant	Placebo
Number of Participants Analyzed [units: participants]	**0**	**0**
Percent Change From Baseline in TC at Week 12		

No statistical analysis provided for Percent Change From Baseline in TC at Week 12

12. Secondary: Percent Change From Baseline in LDL-C at Week 4 [Time Frame: Baseline and Week 4]

Measure Type	Secondary
Measure Title	Percent Change From Baseline in LDL-C at Week 4
Measure Description	No text entered.

Time Frame	Baseline and Week 4
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.
Study was terminated. Efficacy endpoints were not summarized and no planned efficacy analyses were performed.

Reporting Groups

	Description
Extended-release Niacin/Laropiprant	ERN/LRPT 1 g (1 tablet for 4 wks) followed by ERN/LRPT 2 g (2 tablets for 8 wks); Each 1-g tablet contains 1 g of ER niacin and 20 mg of laropiprant.
Placebo	Matching 1 g Placebo (1 tablet for 4 wks) followed by 2 g placebo (2 tablets for 8 weeks)

Measured Values

	Extended-release Niacin/Laropiprant	**Placebo**
Number of Participants Analyzed [units: participants]	**0**	**0**
Percent Change From Baseline in LDL-C at Week 4		

No statistical analysis provided for Percent Change From Baseline in LDL-C at Week 4

13. Secondary: Percent Change From Baseline in LDL-C:HDL-C at Week 4 [Time Frame: Baseline and Week 4]

Measure Type	Secondary
Measure Title	Percent Change From Baseline in LDL-C:HDL-C at Week 4
Measure Description	No text entered.
Time Frame	Baseline and Week 4
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.
Study was terminated. Efficacy endpoints were not summarized and no planned efficacy analyses were performed.

Reporting Groups

	Description
Extended-release Niacin/Laropiprant	ERN/LRPT 1 g (1 tablet for 4 wks) followed by ERN/LRPT 2 g (2 tablets for 8 wks); Each 1-g tablet contains 1 g of ER niacin and 20 mg of laropiprant.
Placebo	Matching 1 g Placebo (1 tablet for 4 wks) followed by 2 g placebo (2 tablets for 8 weeks)

Measured Values

	Extended-release Niacin/Laropiprant	Placebo
Number of Participants Analyzed [units: participants]	**0**	**0**
Percent Change From Baseline in LDL-C:HDL-C at Week 4		

No statistical analysis provided for Percent Change From Baseline in LDL-C:HDL-C at Week 4

14. Secondary: Percent Change From Baseline in HDL-C at Week 4 [Time Frame: Baseline and Week 4]

Measure Type	Secondary
Measure Title	Percent Change From Baseline in HDL-C at Week 4
Measure Description	No text entered.
Time Frame	Baseline and Week 4
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.
Study was terminated. Efficacy endpoints were not summarized and no planned efficacy analyses were performed.

Reporting Groups

	Description
Extended-release Niacin/Laropiprant	ERN/LRPT 1 g (1 tablet for 4 wks) followed by ERN/LRPT 2 g (2 tablets for 8 wks); Each 1-g tablet contains 1 g of ER niacin and 20 mg of laropiprant.
Placebo	Matching 1 g Placebo (1 tablet for 4 wks) followed by 2 g placebo (2 tablets for 8 weeks)

Measured Values

	Extended-release Niacin/Laropiprant	Placebo
Number of Participants Analyzed [units: participants]	**0**	**0**
Percent Change From Baseline in HDL-C at Week 4		

No statistical analysis provided for Percent Change From Baseline in HDL-C at Week 4

15. Secondary: Percent Change From Baseline in TG at Week 4 [Time Frame: Baseline and Week 4]

Measure Type	Secondary
Measure Title	Percent Change From Baseline in TG at Week 4
Measure Description	No text entered.

Time Frame	Baseline and Week 4
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.
Study was terminated. Efficacy endpoints were not summarized and no planned efficacy analyses were performed.

Reporting Groups

	Description
Extended-release Niacin/Laropiprant	ERN/LRPT 1 g (1 tablet for 4 wks) followed by ERN/LRPT 2 g (2 tablets for 8 wks); Each 1-g tablet contains 1 g of ER niacin and 20 mg of laropiprant.
Placebo	Matching 1 g Placebo (1 tablet for 4 wks) followed by 2 g placebo (2 tablets for 8 weeks)

Measured Values

	Extended-release Niacin/Laropiprant	**Placebo**
Number of Participants Analyzed [units: participants]	**0**	**0**
Percent Change From Baseline in TG at Week 4		

No statistical analysis provided for Percent Change From Baseline in TG at Week 4

16. Secondary: Percent Change From Baseline in Non-HDL-C at Week 4 [Time Frame: Baseline and Week 4]

Measure Type	Secondary
Measure Title	Percent Change From Baseline in Non-HDL-C at Week 4
Measure Description	No text entered.
Time Frame	Baseline and Week 4
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.
Study was terminated. Efficacy endpoints were not summarized and no planned efficacy analyses were performed.

Reporting Groups

	Description
Extended-release Niacin/Laropiprant	ERN/LRPT 1 g (1 tablet for 4 wks) followed by ERN/LRPT 2 g (2 tablets for 8 wks); Each 1-g tablet contains 1 g of ER niacin and 20 mg of laropiprant.
Placebo	Matching 1 g Placebo (1 tablet for 4 wks) followed by 2 g placebo (2 tablets for 8 weeks)

Measured Values

	Extended-release Niacin/Laropiprant	Placebo
Number of Participants Analyzed [units: participants]	**0**	**0**
Percent Change From Baseline in Non-HDL-C at Week 4		

No statistical analysis provided for Percent Change From Baseline in Non-HDL-C at Week 4

17. Secondary: Percent Change From Baseline in Apo B at Week 4 [Time Frame: Baseline and Week 4]

Measure Type	Secondary
Measure Title	Percent Change From Baseline in Apo B at Week 4
Measure Description	No text entered.
Time Frame	Baseline and Week 4
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.
Study was terminated. Efficacy endpoints were not summarized and no planned efficacy analyses were performed.

Reporting Groups

	Description
Extended-release Niacin/Laropiprant	ERN/LRPT 1 g (1 tablet for 4 wks) followed by ERN/LRPT 2 g (2 tablets for 8 wks); Each 1-g tablet contains 1 g of ER niacin and 20 mg of laropiprant.
Placebo	Matching 1 g Placebo (1 tablet for 4 wks) followed by 2 g placebo (2 tablets for 8 weeks)

Measured Values

	Extended-release Niacin/Laropiprant	Placebo
Number of Participants Analyzed [units: participants]	**0**	**0**
Percent Change From Baseline in Apo B at Week 4		

No statistical analysis provided for Percent Change From Baseline in Apo B at Week 4

18. Secondary: Percent Change From Baseline in Apo B:Apo A-I at Week 4 [Time Frame: Baseline and Week 4]

Measure Type	Secondary
Measure Title	Percent Change From Baseline in Apo B:Apo A-I at Week 4
Measure Description	No text entered.

Time Frame	Baseline and Week 4
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.
Study was terminated. Efficacy endpoints were not summarized and no planned efficacy analyses were performed.

Reporting Groups

	Description
Extended-release Niacin/Laropiprant	ERN/LRPT 1 g (1 tablet for 4 wks) followed by ERN/LRPT 2 g (2 tablets for 8 wks); Each 1-g tablet contains 1 g of ER niacin and 20 mg of laropiprant.
Placebo	Matching 1 g Placebo (1 tablet for 4 wks) followed by 2 g placebo (2 tablets for 8 weeks)

Measured Values

	Extended-release Niacin/Laropiprant	**Placebo**
Number of Participants Analyzed [units: participants]	**0**	**0**
Percent Change From Baseline in Apo B:Apo A-I at Week 4		

No statistical analysis provided for Percent Change From Baseline in Apo B:Apo A-I at Week 4

19. Secondary: Percent Change From Baseline in TC:HDL-C at Week 4 [Time Frame: Baseline and Week 4]

Measure Type	Secondary
Measure Title	Percent Change From Baseline in TC:HDL-C at Week 4
Measure Description	No text entered.
Time Frame	Baseline and Week 4
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.
Study was terminated. Efficacy endpoints were not summarized and no planned efficacy analyses were performed.

Reporting Groups

	Description
Extended-release Niacin/Laropiprant	ERN/LRPT 1 g (1 tablet for 4 wks) followed by ERN/LRPT 2 g (2 tablets for 8 wks); Each 1-g tablet contains 1 g of ER niacin and 20 mg of laropiprant.
Placebo	Matching 1 g Placebo (1 tablet for 4 wks) followed by 2 g placebo (2 tablets for 8 weeks)

Measured Values

	Extended-release Niacin/Laropiprant	Placebo
Number of Participants Analyzed [units: participants]	**0**	**0**
Percent Change From Baseline in TC:HDL-C at Week 4		

No statistical analysis provided for Percent Change From Baseline in TC:HDL-C at Week 4

20. Secondary: Percent Change From Baseline in Lp(a) at Week 4 [Time Frame: Baseline and Week 4]

Measure Type	Secondary
Measure Title	Percent Change From Baseline in Lp(a) at Week 4
Measure Description	No text entered.
Time Frame	Baseline and Week 4
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.
Study was terminated. Efficacy endpoints were not summarized and no planned efficacy analyses were performed.

Reporting Groups

	Description
Extended-release Niacin/Laropiprant	ERN/LRPT 1 g (1 tablet for 4 wks) followed by ERN/LRPT 2 g (2 tablets for 8 wks); Each 1-g tablet contains 1 g of ER niacin and 20 mg of laropiprant.
Placebo	Matching 1 g Placebo (1 tablet for 4 wks) followed by 2 g placebo (2 tablets for 8 weeks)

Measured Values

	Extended-release Niacin/Laropiprant	Placebo
Number of Participants Analyzed [units: participants]	**0**	**0**
Percent Change From Baseline in Lp(a) at Week 4		

No statistical analysis provided for Percent Change From Baseline in Lp(a) at Week 4

21. Secondary: Percent Change From Baseline in Apo A-I at Week 4 [Time Frame: Baseline and Week 4]

Measure Type	Secondary
Measure Title	Percent Change From Baseline in Apo A-I at Week 4
Measure Description	No text entered.

Time Frame	Baseline and Week 4
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.
Study was terminated. Efficacy endpoints were not summarized and no planned efficacy analyses were performed.

Reporting Groups

	Description
Extended-release Niacin/Laropiprant	ERN/LRPT 1 g (1 tablet for 4 wks) followed by ERN/LRPT 2 g (2 tablets for 8 wks); Each 1-g tablet contains 1 g of ER niacin and 20 mg of laropiprant.
Placebo	Matching 1 g Placebo (1 tablet for 4 wks) followed by 2 g placebo (2 tablets for 8 weeks)

Measured Values

	Extended-release Niacin/Laropiprant	**Placebo**
Number of Participants Analyzed [units: participants]	**0**	**0**
Percent Change From Baseline in Apo A-I at Week 4		

No statistical analysis provided for Percent Change From Baseline in Apo A-I at Week 4

22. Secondary: Percent Change From Baseline in TC at Week 4 [Time Frame: Baseline and Week 4]

Measure Type	Secondary
Measure Title	Percent Change From Baseline in TC at Week 4
Measure Description	No text entered.
Time Frame	Baseline and Week 4
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.
Study was terminated. Efficacy endpoints were not summarized and no planned efficacy analyses were performed.

Reporting Groups

	Description
Extended-release Niacin/Laropiprant	ERN/LRPT 1 g (1 tablet for 4 wks) followed by ERN/LRPT 2 g (2 tablets for 8 wks); Each 1-g tablet contains 1 g of ER niacin and 20 mg of laropiprant.
Placebo	Matching 1 g Placebo (1 tablet for 4 wks) followed by 2 g placebo (2 tablets for 8 weeks)

Measured Values

	Extended-release Niacin/Laropiprant	Placebo
Number of Participants Analyzed [units: participants]	**0**	**0**
Percent Change From Baseline in TC at Week 4		

No statistical analysis provided for Percent Change From Baseline in TC at Week 4

23. Secondary: Number of Participants Who Achieve LDL-C Target Levels at Week 12 of Treatment [Time Frame: Baseline and 12 weeks]

Measure Type	Secondary
Measure Title	Number of Participants Who Achieve LDL-C Target Levels at Week 12 of Treatment
Measure Description	assessed as per National Cholesterol Education Program (NCEP) Adult Treatment Panel III (ATP III) and European Society of Cardiology (ESC) treatment guidelines
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.
Study was terminated. Efficacy endpoints were not summarized and no planned efficacy analyses were performed.

Reporting Groups

	Description
Extended-release Niacin/Laropiprant	ERN/LRPT 1 g (1 tablet for 4 wks) followed by ERN/LRPT 2 g (2 tablets for 8 wks); Each 1-g tablet contains 1 g of ER niacin and 20 mg of laropiprant.
Placebo	Matching 1 g Placebo (1 tablet for 4 wks) followed by 2 g placebo (2 tablets for 8 weeks)

Measured Values

	Extended-release Niacin/Laropiprant	Placebo
Number of Participants Analyzed [units: participants]	**0**	**0**
Number of Participants Who Achieve LDL-C Target Levels at Week 12 of Treatment		

No statistical analysis provided for Number of Participants Who Achieve LDL-C Target Levels at Week 12 of Treatment

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	up to 12 weeks

Additional Description	The All Patients as Treated (APaT) population, which consisted of all randomized participants who received at least one dose of study treatment post randomization.

Reporting Groups

	Description
Extended-release Niacin/Laropiprant	ERN/LRPT 1 g (1 tablet for 4 wks) followed by ERN/LRPT 2 g (2 tablets for 8 wks); Each 1-g tablet contains 1 g of ER niacin and 20 mg of laropiprant.
Placebo	Matching 1 g Placebo (1 tablet for 4 wks) followed by 2 g placebo (2 tablets for 8 weeks)

Serious Adverse Events

	Extended-release Niacin/Laropiprant	Placebo
Total, serious adverse events		
# participants affected / at risk	**23/572 (4.02%)**	**16/572 (2.80%)**
Cardiac disorders		
Angina unstable † 1		
# participants affected / at risk	**1/572 (0.17%)**	**1/572 (0.17%)**
# events	**1**	**1**
Aortic valve stenosis † 1		
# participants affected / at risk	**1/572 (0.17%)**	**0/572 (0.00%)**
# events	**1**	**0**
Atrial fibrillation † 1		
# participants affected / at risk	**1/572 (0.17%)**	**0/572 (0.00%)**
# events	**1**	**0**
Bradycardia † 1		
# participants affected / at risk	**1/572 (0.17%)**	**0/572 (0.00%)**
# events	**1**	**0**
Cardiac failure congestive † 1		
# participants affected / at risk	**2/572 (0.35%)**	**0/572 (0.00%)**
# events	**2**	**0**
Cardiogenic shock † 1		
# participants affected / at risk	**0/572 (0.00%)**	**1/572 (0.17%)**
# events	**0**	**1**
Coronary artery disease † 1		
# participants affected / at risk	**1/572 (0.17%)**	**1/572 (0.17%)**
# events	**1**	**1**
Ear and labyrinth disorders		
Vertigo † 1		
# participants affected / at risk	**1/572 (0.17%)**	**0/572 (0.00%)**
# events	**1**	**0**
Gastrointestinal disorders		
Constipation † 1		
# participants affected / at risk	**0/572 (0.00%)**	**1/572 (0.17%)**
# events	**0**	**1**

General disorders		
Non-cardiac chest pain † 1		
# participants affected / at risk	**1/572 (0.17%)**	**2/572 (0.35%)**
# events	**1**	**2**
Sudden cardiac death † 1		
# participants affected / at risk	**1/572 (0.17%)**	**0/572 (0.00%)**
# events	**1**	**0**
Infections and infestations		
Epiglottitis † 1		
# participants affected / at risk	**1/572 (0.17%)**	**0/572 (0.00%)**
# events	**1**	**0**
Gastroenteritis † 1		
# participants affected / at risk	**1/572 (0.17%)**	**1/572 (0.17%)**
# events	**1**	**1**
Pneumonia † 1		
# participants affected / at risk	**0/572 (0.00%)**	**1/572 (0.17%)**
# events	**0**	**1**
Puncture site infection † 1		
# participants affected / at risk	**1/572 (0.17%)**	**0/572 (0.00%)**
# events	**1**	**0**
Injury, poisoning and procedural complications		
Contusion † 1		
# participants affected / at risk	**1/572 (0.17%)**	**0/572 (0.00%)**
# events	**1**	**0**
Meniscus lesion † 1		
# participants affected / at risk	**0/572 (0.00%)**	**1/572 (0.17%)**
# events	**0**	**1**
Metabolism and nutrition disorders		
Hypoglycaemia † 1		
# participants affected / at risk	**1/572 (0.17%)**	**0/572 (0.00%)**
# events	**1**	**0**
Musculoskeletal and connective tissue disorders		
Osteoarthritis † 1		
# participants affected / at risk	**1/572 (0.17%)**	**0/572 (0.00%)**
# events	**1**	**0**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Basal cell carcinoma † 1		
# participants affected / at risk	**0/572 (0.00%)**	**2/572 (0.35%)**
# events	**0**	**2**
Bile duct cancer † 1		
# participants affected / at risk	**1/572 (0.17%)**	**0/572 (0.00%)**
# events	**1**	**0**
Malignant melanoma † 1		

# participants affected / at risk	0/572 (0.00%)	1/572 (0.17%)
# events	0	1
Prostatic adenoma † 1		
# participants affected / at risk	1/572 (0.17%)	0/572 (0.00%)
# events	1	0
Squamous cell carcinoma † 1		
# participants affected / at risk	1/572 (0.17%)	0/572 (0.00%)
# events	1	0
Uterine leiomyoma † 1		
# participants affected / at risk	1/572 (0.17%)	0/572 (0.00%)
# events	1	0
Nervous system disorders		
Cerebrovascular accident † 1		
# participants affected / at risk	2/572 (0.35%)	0/572 (0.00%)
# events	2	0
Haemorrhage intracranial † 1		
# participants affected / at risk	0/572 (0.00%)	1/572 (0.17%)
# events	0	1
Syncope † 1		
# participants affected / at risk	1/572 (0.17%)	0/572 (0.00%)
# events	1	0
Psychiatric disorders		
Depression † 1		
# participants affected / at risk	0/572 (0.00%)	1/572 (0.17%)
# events	0	1
Renal and urinary disorders		
Renal failure acute † 1		
# participants affected / at risk	0/572 (0.00%)	1/572 (0.17%)
# events	0	1
Urinary retention † 1		
# participants affected / at risk	1/572 (0.17%)	0/572 (0.00%)
# events	1	0
Reproductive system and breast disorders		
Postmenopausal haemorrhage † 1		
# participants affected / at risk	0/572 (0.00%)	1/572 (0.17%)
# events	0	1
Respiratory, thoracic and mediastinal disorders		
Chronic obstructive pulmonary disease † 1		
# participants affected / at risk	0/572 (0.00%)	1/572 (0.17%)
# events	0	1
Dyspnoea † 1		
# participants affected / at risk	1/572 (0.17%)	1/572 (0.17%)
# events	1	1
Epistaxis † 1		

# participants affected / at risk	**1/572 (0.17%)**	**0/572 (0.00%)**
# events	**1**	**0**
Sleep apnoea syndrome † 1		
# participants affected / at risk	**0/572 (0.00%)**	**1/572 (0.17%)**
# events	**0**	**1**
Skin and subcutaneous tissue disorders		
Pruritus † 1		
# participants affected / at risk	**1/572 (0.17%)**	**0/572 (0.00%)**
# events	**1**	**0**
Vascular disorders		
Accelerated hypertension † 1		
# participants affected / at risk	**1/572 (0.17%)**	**1/572 (0.17%)**
# events	**1**	**1**
Diabetic macroangiopathy † 1		
# participants affected / at risk	**1/572 (0.17%)**	**0/572 (0.00%)**
# events	**1**	**0**
Flushing † 1		
# participants affected / at risk	**1/572 (0.17%)**	**0/572 (0.00%)**
# events	**1**	**0**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA 15.1

Other Adverse Events

Hide Other Adverse Events

Time Frame	up to 12 weeks
Additional Description	The All Patients as Treated (APaT) population, which consisted of all randomized participants who received at least one dose of study treatment post randomization.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Extended-release Niacin/Laropiprant	ERN/LRPT 1 g (1 tablet for 4 wks) followed by ERN/LRPT 2 g (2 tablets for 8 wks); Each 1-g tablet contains 1 g of ER niacin and 20 mg of laropiprant.
Placebo	Matching 1 g Placebo (1 tablet for 4 wks) followed by 2 g placebo (2 tablets for 8 weeks)

Other Adverse Events

	Extended-release Niacin/Laropiprant	**Placebo**
Total, other (not including serious) adverse events		
# participants affected / at risk	**101/572 (17.66%)**	**16/572 (2.80%)**

Skin and subcutaneous tissue disorders		
Pruritus † 1		
# participants affected / at risk	**45/572 (7.87%)**	**3/572 (0.52%)**
# events	**52**	**3**
Vascular disorders		
Flushing † 1		
# participants affected / at risk	**66/572 (11.54%)**	**13/572 (2.27%)**
# events	**100**	**18**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA 15.1

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

MK-0524A-133 was stopped prior to completion. Raw individual efficacy data were obtained but none of planned efficacy outcomes were summarized or analyzed. Only safety data were summarized.

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: 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. Any information identified by the SPONSOR as confidential must be deleted prior to submission. SPONSOR review can be expedited to meet publication timelines.

Results Point of Contact:

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Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT01274559 History of Changes
Other Study ID Numbers:	0524A-133 CTRI/2012/08/002857 (Registry Identifier: CTRI)
Study First Received:	October 25, 2010
Results First Received:	January 30, 2014
Last Updated:	April 27, 2015
Health Authority:	United States: Food and Drug Administration

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