Extended Niacin/Laropiprant in Patients With Type 2 Diabetes (0524A-069)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

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

ClinicalTrials.gov Identifier:
NCT00485758

First received: June 12, 2007
Last updated: October 9, 2015
Last verified: October 2015
History of Changes

Purpose

A study to assess the efficacy and tolerability of ER (Extended Release) niacin/laropiprant versus placebo in Type 2 Diabetes Mellitus patients.

Condition	Intervention	Phase
Diabetes Mellitus Type 2	Drug: ER niacin/laropiprant Drug: Comparator : placebo (unspecified)	Phase 3

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Safety/Efficacy Study
Intervention Model: Parallel Assignment
Masking: Double Blind (Subject, Investigator)
Primary Purpose: Treatment

Official Title: A Multicenter, Randomized, Double-Blind, Placebo Controlled 36 Week Study to Evaluate the Efficacy and Safety of Extended Release (ER) Niacin/Laropiprant in Patients With Type 2 Diabetes

Resource links provided by NLM:

MedlinePlus related topics: Diabetes Type 2

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 at Week (Wk) 12 Compared to Baseline (Bl) in Low-density Lipoprotein Cholesterol in Patients With Type 2 Diabetes When Compared to Placebo [Time Frame: Baseline and 12 Weeks] [Designated as safety issue: No]

After 12 Weeks of treatment, to assess the reduction of low-density lipoprotein cholesterol in patients with Type 2 diabetes when compared to placebo

Secondary Outcome Measures:

- Percent Change at Week (Wk) 12 Compared to Baseline (Bl) in High Density Lipoprotein Cholesterol in Patients With Type 2 Diabetes When Compared to Placebo [Time Frame: Baseline and 12 Weeks] [Designated as safety issue: No]

  After 12 weeks of treatment, to assess the increase of high-density lipoprotein cholesterol in patients with Type 2 diabetes when compared to placebo

- Percent Change at Week (Wk) 12 Compared to Baseline (Bl) in Triglycerides in Patients With Type 2 Diabetes When Compared to Placebo [Time Frame: Baseline and 12 Weeks] [Designated as safety issue: No]

  after 12 weeks of treatment, to assess the reduction of triglycerides in patients with Type 2 diabetes when compared to placebo

Enrollment:	796
Study Start Date:	July 2007
Study Completion Date:	August 2008
Primary Completion Date:	August 2008 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
1 Arm 1: One tablet of ER niacin/ laropiprant (1g) + one tablet of the run-in statin dose, advancing to ER niacin/laropiprant (2g) at Week 4 for the remainder of the study.	Drug: ER niacin/laropiprant One tablet of ER niacin/laropiprant (1g); advancing to ER niacin/laropiprant (2g) at Week 4 for the remainder of the study 36 Weeks. Other Names: • MK0524A • CORDAPTIVE™ • laropiprant (+) niacin
Active Comparator: 2 Arm 2: stable lipid-modifying regimen, adding Placebo ER niacin/laropiprant in week 4, for the duration of the study.	Drug: Comparator : placebo (unspecified) ER niacin/laropiprant Placebo

Eligibility

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

Criteria

Inclusion Criteria:

- Patients between the ages of 18 to 80 years with Type 2 Diabetes who are on a stable dose of antidiabetic medication for at least 3 months

Exclusion Criteria:

- Patients taking Cholestin, niacin (>50 mg/day), fibrate therapy, hormonal contraceptives, intermittent Hormone Replacement Therapy, or certain corticosteroids
- Patients with any of the following conditions: active liver disease or kidney disease, poorly controlled high blood pressure, active peptic ulcer, or other heart or blood diseases
- Patients with abnormal laboratory results from a blood test that will be given before starting the study

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: NCT00485758

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) EXIT

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

Publications:

MacLean A, McKenney J, Scott R, Brinton E, Bays H, Mitchel Y, Paolini J, Giezek H, Vandormael K, Ruck RA, Gibson K, Sisk CM, Maccubbin D. Efficacy and safety of extended release niacin/laropiprant in patients with type 2 diabetes mellitus. Br J Cardiol. 2011;18(1):37-45.

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

Bays HE, Brinton EA, Triscari J, Chen E, Maccubbin D, MacLean AA, Gibson KL, Ruck RA, Johnson-Levonas AO, O'Neill EA, Mitchel YB. Extended-release niacin/laropiprant significantly improves lipid levels in type 2 diabetes mellitus irrespective of baseline glycemic control. Vasc Health Risk Manag. 2015 Feb 24;11:165-72. doi: 10.2147/VHRM.S70907. eCollection 2015.

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, Giezek H, McKenney JM, O'Neill EA, Tershakovec AM. Extended-release niacin/laropiprant effects on lipoprotein subfractions in patients with type 2 diabetes mellitus. Metab Syndr Relat Disord. 2012 Aug;10(4):260-6. doi: 10.1089/met.2012.0005. Epub 2012 Mar 8.

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:	NCT00485758 History of Changes
Other Study ID Numbers:	0524A-069 MK0524A-069 2007_543
Study First Received:	June 12, 2007
Results First Received:	August 4, 2009
Last Updated:	October 9, 2015
Health Authority:	United States: Food and Drug Administration

Additional relevant MeSH terms:

Diabetes Mellitus, Type 2	Hypolipidemic Agents
Diabetes Mellitus	Lipid Regulating Agents
Endocrine System Diseases	Micronutrients
Glucose Metabolism Disorders	Molecular Mechanisms of Pharmacological Action
Metabolic Diseases	Pharmacologic Actions
Niacin	Physiological Effects of Drugs
Niacinamide	Therapeutic Uses
Nicotinic Acids	Vasodilator Agents
Antimetabolites	Vitamin B Complex
Cardiovascular Agents	Vitamins
Growth Substances	

ClinicalTrials.gov processed this record on April 14, 2016

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First received: June 12, 2007
Last updated: October 9, 2015
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History of Changes

Results First Received: August 4, 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
Condition:	Diabetes Mellitus Type 2
Interventions:	Drug: ER niacin/laropiprant Drug: Comparator : placebo (unspecified)

Participant Flow

Hide Participant Flow

Recruitment Details

Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations

First Patient In:13-Aug-2007, Last Patient Last Visit:15-Jan-2009

Ninety-four (94) sites participated: Australia 2 sites; Belgium 7 sites; Canada 6 sites; Ecuador 2 sites; Finland 2 sites; Germany 8 sites; Israel 4 sites; Italy 3 sites; Malaysia 5 sites; New Zealand 4 sites; Portugal 4 sites; Sweden 10 sites; Taiwan 5 sites; United States 32 sites

Pre-Assignment Details

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

Patients with Type 2 Diabetes who were not at protocol specified low-density lipoprotein cholesterol goal of <115 milligrams/deciliter at screening, had a 4-week run-in period of lipid modifying therapy. In order to advance to randomization, patients had to meet the low-density

lipoprotein cholesterol goal.

Reporting Groups

	Description
Extended Release Niacin/Laropiprant	One tablet of Extended Release Niacin/Laropiprant (1 gram/20 milligram) in addition to lipid modifying therapy. After 4 weeks, advanced to Extended Release Niacin/Laropiprant (2 gram/40 milligram). No adjustments were made to any lipid modifying regimen established during run-in until Week 12.
Placebo	Matching placebo added to lipid modifying regimen and continued on this regimen for remainder of the study.

Participant Flow: Overall Study

	Extended Release Niacin/Laropiprant	Placebo
STARTED	**454**	**342**
COMPLETED	**298**	**277**
NOT COMPLETED	**156**	**65**
Adverse Event	**102**	**31**
Death	**0**	**1**
Lost to Follow-up	**5**	**1**
Physician Decision	**3**	**3**
Protocol Violation	**11**	**2**
Withdrawal by Subject	**32**	**27**
Study Terminated by Sponsor	**3**	**0**

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	One tablet of Extended Release Niacin/Laropiprant (1 gram/20 milligram) in addition to lipid modifying therapy. After 4 weeks, advanced to Extended Release Niacin/Laropiprant (2 gram/40 milligram). No adjustments were made to any lipid modifying regimen established during run-in until Week 12.
Placebo	Matching placebo added to lipid modifying regimen and continued on this regimen for remainder of the study.
Total	Total of all reporting groups

Baseline Measures

	Extended Release Niacin/Laropiprant	Placebo	Total
Number of Participants [units: participants]	454	342	796
Age [units: years] Mean (Standard Deviation)	62.0 (9.3)	62.0 (9.4)	62.0 (9.3)
Gender [units: participants]			
Female	188	126	314
Male	266	216	482
Fasting Plasma Glucose [units: milligrams/deciliter] Mean (Standard Deviation)	132.0 (33.9)	133.6 (32.4)	132.7 (33.3)
High-density lipoprotein cholesterol [units: milligrams/deciliter (mg/dl)] Mean (Standard Deviation)	49.93 (13.49)	50.26 (13.23)	50.07 (13.37)
Low-density lipoprotein cholesterol [units: milligrams/deciliter (mg/dl)] Mean (Standard Deviation)	87.19 (20.54)	85.22 (18.00)	86.34 (19.50)
Triglycerides [units: milligrams/deciliter (mg/dl)] Median (Full Range)	126.00 (32.00 to 628.00)	129.00 (39.00 to 509.00)	127.00 (32.00 to 628.00)

Outcome Measures

Hide All Outcome Measures

1. Primary: Percent Change at Week (Wk) 12 Compared to Baseline (Bl) in Low-density Lipoprotein Cholesterol in Patients With Type 2 Diabetes When Compared to Placebo [Time Frame: Baseline and 12 Weeks]

Measure Type	Primary
Measure Title	Percent Change at Week (Wk) 12 Compared to Baseline (Bl) in Low-density Lipoprotein Cholesterol in Patients With Type 2 Diabetes When Compared to Placebo
Measure Description	After 12 Weeks of treatment, to assess the reduction of low-density lipoprotein cholesterol in patients with Type 2 diabetes when compared to placebo
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

Extended Release Niacin/Laropiprant	One tablet of Extended Release Niacin/Laropiprant (1 gram/20 milligram) in addition to lipid modifying therapy. After 4 weeks, advanced to Extended Release Niacin/Laropiprant (2 gram/40 milligram). No adjustments were made to any lipid modifying regimen established during run-in until Week 12.
Placebo	Matching placebo added to lipid modifying regimen and continued on this regimen for remainder of the study.

Measured Values

	Extended Release Niacin/Laropiprant	**Placebo**
Number of Participants Analyzed [units: participants]	**432**	**336**
Percent Change at Week (Wk) 12 Compared to Baseline (Bl) in Low-density Lipoprotein Cholesterol in Patients With Type 2 Diabetes When Compared to Placebo [units: Percent change at Wk 12 compared to Bl] Least Squares Mean (95% Confidence Interval)	**-15.8 (-18.4 to -13.2)**	**2.1 (0.3 to 4.6)**

Statistical Analysis 1 for Percent Change at Week (Wk) 12 Compared to Baseline (Bl) in Low-density Lipoprotein Cholesterol in Patients With Type 2 Diabetes When Compared to Placebo

Groups [1]	All groups
Method [2]	Wilcoxon (Mann-Whitney)
P Value [3]	<0.001
Mean Difference (Final Values) [4]	-17.9
Standard Error of the mean	(1.8)
95% Confidence Interval	-21.4 to -14.4

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Study times: 4, 8 and 12 weeks. Terms: treatment-by-time, gender-by-time and baseline low-density lipoprotein cholesterol -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 at Week (Wk) 12 Compared to Baseline (Bl) in High Density Lipoprotein Cholesterol in Patients With Type 2 Diabetes When Compared to Placebo [Time Frame: Baseline and 12 Weeks]

Measure Type	Secondary
Measure Title	Percent Change at Week (Wk) 12 Compared to Baseline (Bl) in High Density Lipoprotein Cholesterol in Patients With Type 2 Diabetes When Compared to Placebo

Measure Description	After 12 weeks of treatment, to assess the increase of high-density lipoprotein cholesterol in patients with Type 2 diabetes when compared to placebo
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
Extended Release Niacin/Laropiprant	One tablet of Extended Release Niacin/Laropiprant (1 gram/20 milligram) in addition to lipid modifying therapy. After 4 weeks, advanced to Extended Release Niacin/Laropiprant (2 gram/40 milligram). No adjustments were made to any lipid modifying regimen established during run-in until Week 12.
Placebo	Matching placebo added to lipid modifying regimen and continued on this regimen for remainder of the study.

Measured Values

	Extended Release Niacin/Laropiprant	**Placebo**
Number of Participants Analyzed [units: participants]	**432**	**336**
Percent Change at Week (Wk) 12 Compared to Baseline (Bl) in High Density Lipoprotein Cholesterol in Patients With Type 2 Diabetes When Compared to Placebo [units: Percent change at Wk 12 compared to Bl] Least Squares Mean (95% Confidence Interval)	**25.4 (23.4 to 27.5)**	**2.2 (0.6 to 3.8)**

Statistical Analysis 1 for Percent Change at Week (Wk) 12 Compared to Baseline (Bl) in High Density Lipoprotein Cholesterol in Patients With Type 2 Diabetes When Compared to Placebo

Groups [1]	All groups
Method [2]	Repeated Measures Analysis
P Value [3]	<0.001
Mean Difference (Final Values) [4]	23.2
Standard Error of the mean	(1.3)
95% Confidence Interval	20.7 to 25.7

[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:
	Study times: 4, 8 and 12 weeks. Terms: treatment-by-time, gender-by-time and baseline high-density lipoprotein cholesterol -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 at Week (Wk) 12 Compared to Baseline (Bl) in Triglycerides in Patients With Type 2 Diabetes When Compared to Placebo [Time Frame: Baseline and 12 Weeks]

Measure Type	Secondary
Measure Title	Percent Change at Week (Wk) 12 Compared to Baseline (Bl) in Triglycerides in Patients With Type 2 Diabetes When Compared to Placebo
Measure Description	after 12 weeks of treatment, to assess the reduction of triglycerides in patients with Type 2 diabetes when compared to placebo
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
Extended Release Niacin/Laropiprant	One tablet of Extended Release Niacin/Laropiprant (1 gram/20 milligram) in addition to lipid modifying therapy. After 4 weeks, advanced to Extended Release Niacin/Laropiprant (2 gram/40 milligram). No adjustments were made to any lipid modifying regimen established during run-in until Week 12.
Placebo	Matching placebo added to lipid modifying regimen and continued on this regimen for remainder of the study.

Measured Values

	Extended Release Niacin/Laropiprant	**Placebo**
Number of Participants Analyzed [units: participants]	**400**	**328**
Percent Change at Week (Wk) 12 Compared to Baseline (Bl) in Triglycerides in Patients With Type 2 Diabetes When Compared to Placebo [units: Percent change at Wk 12 compared to Bl] Median (95% Confidence Interval)	**-22.2 (-25.5 to -18.8)**	**2.3 (-1.6 to 6.2)**

Statistical Analysis 1 for Percent Change at Week (Wk) 12 Compared to Baseline (Bl) in Triglycerides in Patients With Type 2 Diabetes When Compared to Placebo

Groups [1]	All groups
Method [2]	ANCOVA
P Value [3]	<0.001

Median Difference (Final Values) [4]	-23.1
95% Confidence Interval	-27.2 to -18.9

[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:
	Nonparametric Analysis of Covariance model based on Tukey's normalized ranks with term for treatment, gender 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:
	The median difference between treatments is based on the Hodges-Lehmann estimates of shift with a corresponding distribution-free Confidence Interval based on Wilcoxon's rank

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	No text entered.
Additional Description	7 randomized patients took no study drug dose and were not included in the safety follow-up

Reporting Groups

	Description
Extended Release Niacin/Laropiprant	One tablet of Extended Release Niacin/Laropiprant (1 gram/20 milligram) in addition to lipid modifying therapy. After 4 weeks, advanced to Extended Release Niacin/Laropiprant (2 gram/40 milligram). No adjustments were made to any lipid modifying regimen established during run-in until Week 12.
Placebo	Matching placebo added to lipid modifying regimen and continued on this regimen for remainder of the study.

Serious Adverse Events

	Extended Release Niacin/Laropiprant	**Placebo**
Total, serious adverse events		
# participants affected / at risk	**26/449 (5.79%)**	**24/340 (7.06%)**
Blood and lymphatic system disorders		
Anaemia * 1		
# participants affected / at risk	**0/449 (0.00%)**	**1/340 (0.29%)**
Cardiac disorders		
Angina pectoris * 1		
# participants affected / at risk	**0/449 (0.00%)**	**1/340 (0.29%)**

Angina unstable [*1]		
# participants affected / at risk	**0/449 (0.00%)**	**2/340 (0.59%)**
Aortic valve stenosis [*1]		
# participants affected / at risk	**1/449 (0.22%)**	**0/340 (0.00%)**
Coronary artery disease [*1]		
# participants affected / at risk	**1/449 (0.22%)**	**2/340 (0.59%)**
Myocardial infarction [*1]		
# participants affected / at risk	**2/449 (0.45%)**	**0/340 (0.00%)**
Eye disorders		
Cataract [*1]		
# participants affected / at risk	**1/449 (0.22%)**	**0/340 (0.00%)**
Gastrointestinal disorders		
Abdominal hernia [*1]		
# participants affected / at risk	**0/449 (0.00%)**	**1/340 (0.29%)**
Diverticulum [*1]		
# participants affected / at risk	**1/449 (0.22%)**	**0/340 (0.00%)**
Gastric ulcer [*1]		
# participants affected / at risk	**1/449 (0.22%)**	**0/340 (0.00%)**
Gastrooesophageal reflux disease [*1]		
# participants affected / at risk	**0/449 (0.00%)**	**1/340 (0.29%)**
Haematochezia [*1]		
# participants affected / at risk	**0/449 (0.00%)**	**1/340 (0.29%)**
Mechanical ileus [*1]		
# participants affected / at risk	**1/449 (0.22%)**	**0/340 (0.00%)**
Pancreatitis [*1]		
# participants affected / at risk	**0/449 (0.00%)**	**1/340 (0.29%)**
Upper gastrointestinal haemorrhage [*1]		
# participants affected / at risk	**0/449 (0.00%)**	**1/340 (0.29%)**
General disorders		
Chest pain [*1]		
# participants affected / at risk	**0/449 (0.00%)**	**1/340 (0.29%)**
Non-cardiac chest pain [*1]		
# participants affected / at risk	**1/449 (0.22%)**	**2/340 (0.59%)**
Hepatobiliary disorders		
Cholecystitis [*1]		
# participants affected / at risk	**1/449 (0.22%)**	**0/340 (0.00%)**
Infections and infestations		
Diverticulitis [*1]		
# participants affected / at risk	**1/449 (0.22%)**	**0/340 (0.00%)**
Enterocolitis infectious [*1]		
# participants affected / at risk	**1/449 (0.22%)**	**0/340 (0.00%)**

Erysipelas [*1]		
# participants affected / at risk	**2/449 (0.45%)**	**1/340 (0.29%)**
Infected skin ulcer [*1]		
# participants affected / at risk	**0/449 (0.00%)**	**1/340 (0.29%)**
Pneumonia [*1]		
# participants affected / at risk	**0/449 (0.00%)**	**1/340 (0.29%)**
Viral infection [*1]		
# participants affected / at risk	**1/449 (0.22%)**	**0/340 (0.00%)**
Injury, poisoning and procedural complications		
Lower limb fracture [*1]		
# participants affected / at risk	**0/449 (0.00%)**	**1/340 (0.29%)**
Meniscus lesion [*1]		
# participants affected / at risk	**1/449 (0.22%)**	**0/340 (0.00%)**
Investigations		
International normalised ratio increased [*1]		
# participants affected / at risk	**1/449 (0.22%)**	**0/340 (0.00%)**
Metabolism and nutrition disorders		
Diabetes mellitus [*1]		
# participants affected / at risk	**1/449 (0.22%)**	**0/340 (0.00%)**
Hyperglycaemia [*1]		
# participants affected / at risk	**1/449 (0.22%)**	**0/340 (0.00%)**
Hypoglycaemia [*1]		
# participants affected / at risk	**1/449 (0.22%)**	**0/340 (0.00%)**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Cervix carcinoma [*1]		
# participants affected / at risk	**1/449 (0.22%)**	**0/340 (0.00%)**
Lipoma [*1]		
# participants affected / at risk	**0/449 (0.00%)**	**1/340 (0.29%)**
Metastases to penis [*1]		
# participants affected / at risk	**0/449 (0.00%)**	**1/340 (0.29%)**
Oesophageal carcinoma [*1]		
# participants affected / at risk	**0/449 (0.00%)**	**1/340 (0.29%)**
Prostate cancer [*1]		
# participants affected / at risk	**1/449 (0.22%)**	**1/340 (0.29%)**
Renal cell carcinoma [*1]		
# participants affected / at risk	**0/449 (0.00%)**	**1/340 (0.29%)**
Nervous system disorders		
Subarachnoid haemorrhage [*1]		
# participants affected / at risk	**0/449 (0.00%)**	**1/340 (0.29%)**
Syncope [*1]		

# participants affected / at risk	0/449 (0.00%)	1/340 (0.29%)
Transient ischaemic attack * 1		
# participants affected / at risk	0/449 (0.00%)	1/340 (0.29%)
Renal and urinary disorders		
Calculus urinary * 1		
# participants affected / at risk	0/449 (0.00%)	1/340 (0.29%)
Renal failure acute * 1		
# participants affected / at risk	2/449 (0.45%)	0/340 (0.00%)
Reproductive system and breast disorders		
Ovarian cyst * 1		
# participants affected / at risk	1/449 (0.22%)	0/340 (0.00%)
Prostatitis * 1		
# participants affected / at risk	1/449 (0.22%)	0/340 (0.00%)
Vascular disorders		
Aortic stenosis * 1		
# participants affected / at risk	1/449 (0.22%)	0/340 (0.00%)
Pelvic venous thrombosis * 1		
# participants affected / at risk	1/449 (0.22%)	0/340 (0.00%)
Subclavian artery stenosis * 1		
# participants affected / at risk	0/449 (0.00%)	1/340 (0.29%)

* 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	7 randomized patients took no study drug dose and were not included in the safety follow-up

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Extended Release Niacin/Laropiprant	One tablet of Extended Release Niacin/Laropiprant (1 gram/20 milligram) in addition to lipid modifying therapy. After 4 weeks, advanced to Extended Release Niacin/Laropiprant (2 gram/40 milligram). No adjustments were made to any lipid modifying regimen established during run-in until Week 12.
Placebo	Matching placebo added to lipid modifying regimen and continued on this regimen for remainder of the study.

Other Adverse Events

	Extended Release Niacin/Laropiprant	Placebo
Total, other (not including serious) adverse events		
# participants affected / at risk	**251/449 (55.90%)**	**113/340 (33.24%)**
Gastrointestinal disorders		
Diarrhoea * 1		
# participants affected / at risk	**41/449 (9.13%)**	**21/340 (6.18%)**
Nausea * 1		
# participants affected / at risk	**24/449 (5.35%)**	**12/340 (3.53%)**
Infections and infestations		
Nasopharyngitis * 1		
# participants affected / at risk	**33/449 (7.35%)**	**25/340 (7.35%)**
Upper respiratory tract infection * 1		
# participants affected / at risk	**28/449 (6.24%)**	**24/340 (7.06%)**
Investigations		
Blood glucose increased * 1		
# participants affected / at risk	**52/449 (11.58%)**	**14/340 (4.12%)**
Nervous system disorders		
Headache * 1		
# participants affected / at risk	**20/449 (4.45%)**	**18/340 (5.29%)**
Skin and subcutaneous tissue disorders		
Pruritus * 1		
# participants affected / at risk	**71/449 (15.81%)**	**9/340 (2.65%)**
Rash * 1		
# participants affected / at risk	**26/449 (5.79%)**	**5/340 (1.47%)**
Vascular disorders		
Flushing * 1		
# participants affected / at risk	**79/449 (17.59%)**	**16/340 (4.71%)**

* 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:

MacLean A, McKenney J, Scott R, Brinton E, Bays H, Mitchel Y, Paolini J, Giezek H, Vandormael K, Ruck RA, Gibson K, Sisk CM, Maccubbin D. Efficacy and safety of extended release niacin/laropiprant in patients with type 2 diabetes mellitus. Br J Cardiol. 2011;18(1):37-45.

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

Bays HE, Brinton EA, Triscari J, Chen E, Maccubbin D, MacLean AA, Gibson KL, Ruck RA, Johnson-Levonas AO, O'Neill EA, Mitchel YB. Extended-release niacin/laropiprant significantly improves lipid levels in type 2 diabetes mellitus irrespective of baseline glycemic control. Vasc Health Risk Manag. 2015 Feb 24;11:165-72. doi: 10.2147/VHRM.S70907. eCollection 2015.

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, Giezek H, McKenney JM, O'Neill EA, Tershakovec AM. Extended-release niacin/laropiprant effects on lipoprotein subfractions in patients with type 2 diabetes mellitus. Metab Syndr Relat Disord. 2012 Aug;10(4):260-6. doi: 10.1089/met.2012.0005. Epub 2012 Mar 8.

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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