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Trial record **2 of 3** for: implitapide

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Implitapide in Patients With Homozygous Familial Hypercholesterolemia (HoFH) on Maximal Concurrent Lipid-Lowering Therapy

This study has been terminated.

Sponsor:
Medical Research Laboratories International

Information provided by:
Medical Research Laboratories International

ClinicalTrials.gov Identifier:
NCT00079846

First received: March 17, 2004
Last updated: June 23, 2005
Last verified: April 2005
History of Changes

Full Text View | Tabular View | No Study Results Posted | Disclaimer | How to Read a Study Record

Purpose

The purpose of this study is to determine if **implitapide**, used in conjunction with other lipid-lowering therapies, is safe and effective when compared to placebo in lowering low-density lipoprotein cholesterol (LDL-C) in patients with homozygous familial hypercholesterolemia (HoFH).

Condition	Intervention	Phase
Familial Hypercholesterolemia	Drug: **Implitapide**	Phase 2

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Safety/Efficacy Study
Intervention Model: Single Group Assignment
Masking: Double-Blind
Primary Purpose: Treatment

Official Title: Safety and Efficacy Study of **Implitapide** Compared With Placebo in Patients With Homozygous Familial Hypercholesterolemia (HoFH) on Maximal Concurrent Lipid-Lowering Therapy

Resource links provided by NLM:

Genetics Home Reference related topics: Chanarin-Dorfman syndrome cholesteryl ester storage disease Farber lipogranulomatosis hypercholesterolemia

MedlinePlus related topics: Cholesterol

U.S. FDA Resources

Further study details as provided by Medical Research Laboratories International:

Estimated Enrollment: 60
Study Start Date: September 2003
Estimated Study Completion Date: April 2005

Eligibility

Ages Eligible for Study: 8 Years to 70 Years
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria
Inclusion Criteria:

In order to participate in this study, patients must meet all of the following inclusion criteria:

- be between 8 and 70 years old with a diagnosis of HoFH;
- be stable on and maintain concomitant therapy with hypolipidemic drugs or treatments;
- have an appropriate calculated, fasting LDL-C levels and an appropriate triglyceride (TG) level;
- be male or nonpregnant, nonlactating female;
- give informed consent; and
- meet body weight and height requirements.

Exclusion Criteria:

In order to participate in this study, patients must not meet any of the following exclusion criteria:

- recent myocardial infarction, percutaneous transluminal coronary intervention, coronary artery bypass graft surgery, or cerebrovascular accident;
- uncontrolled hypothyroidism or other uncontrolled endocrine disease;
- known, clinically significant eye abnormalities (e.g., cataracts);
- appropriate serum creatinine phosphokinase levels;
- history of liver disease or liver enzyme levels above appropriate levels;
- alkaline phosphatase above appropriate levels;
- liver cirrhosis and severe liver steatosis;
- clinically significant infection, malignancy, or psychosis;
- use of oral anticoagulants or digoxin, unless the dose has been stable for 4 weeks;
- participation in any other investigational study, including device or observational studies, within 30 days;
- lactating or have a positive serum pregnancy test;
- history of or current drug or alcohol abuse; or
- unwillingness to comply with study procedures, including follow-up, as specified by this protocol, or unwillingness to cooperate fully with the investigator.

▶ Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier: NCT00079846

Locations

United States, Ohio

Metabolic and Atherosclerosis Research Center
Cincinnati, Ohio, United States, 45229

Canada, Quebec

Lipid Clinic and Community Genomic Center, Complexe Hospitalier de la Sagamie
Chicoutimi, Quebec, Canada, G7H 5H6

Lipid Research Center, CHUL du CHUQ
Sainte-Foy, Quebec, Canada, G1V 4G2

Israel

Hadassah University Hospital
Jerusalem, Israel, 91120

Netherlands

Academic Medical Center Amsterdam
Amsterdam, Netherlands, 1105 AZ

Norway

Lipidklinikken - Rikshospitalet
Oslo, Norway, N-0027

Sponsors and Collaborators

Medical Research Laboratories International

▶ More Information

No publications provided

ClinicalTrials.gov Identifier:	NCT00079846 History of Changes
Other Study ID Numbers:	MRL 2002-001
Study First Received:	March 17, 2004
Last Updated:	June 23, 2005
Health Authority:	United States: Food and Drug Administration

Keywords provided by Medical Research Laboratories International:
Homozygous Familial Hypercholesterolemia (HoFH)

Additional relevant MeSH terms:

Hypercholesterolemia	Metabolic Diseases
Hyperlipoproteinemia Type II	Lipid Metabolism, Inborn Errors
Hyperlipidemias	Metabolism, Inborn Errors
Dyslipidemias	Genetic Diseases, Inborn
Lipid Metabolism Disorders	Hyperlipoproteinemias

ClinicalTrials.gov processed this record on September 02, 2013