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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.

ClinicalTrials.gov Identifier:

NCT00079846

**Sponsor:**

Medical Research Laboratories International

First received: March 17, 2004

Last updated: June 23, 2005

**Information provided by:**

Medical Research Laboratories International

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: <b>Implitapide</b>	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

Hyperlipoproteinemia Type II

Hyperlipidemias

Dyslipidemias

Lipid Metabolism Disorders

Metabolic Diseases

Lipid Metabolism, Inborn Errors

Metabolism, Inborn Errors

Genetic Diseases, Inborn

Hyperlipoproteinemias

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