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Trial record 1 of 3 for: implitapide

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## Implitapide in Patients With Hypertriglyceridemia (HTG) on Maximal, Concurrent Triglyceride-Lowering Therapy

This study has been terminated.

ClinicalTrials.gov Identifier:

**Sponsor:**

Medical Research Laboratories International

NCT00080132

First received: March 23, 2004

Last updated: June 23, 2005

**Information provided by:**

Medical Research Laboratories International

Last verified: April 2005

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[No Study Results Posted](#)

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### ► Purpose

The purpose of this study is to determine if **implitapide** is effective in lowering triglyceride (TG) levels in patients with Fredrickson Type I or V hypertriglyceridemia where the maximum tolerable medication and diet were not sufficient.

Condition	Intervention	Phase
Hypertriglyceridemia	Drug: <b>implitapide</b>	Phase 2

Study Type: Interventional

Study Design: Endpoint Classification: Safety/Efficacy Study

Masking: Open Label

Primary Purpose: Treatment

Official Title: An Open-Label, Dose-Escalating Efficacy and Safety Study of **implitapide** in Patients With Hypertriglyceridemia (HTG) on Maximal, Concurrent Triglyceride-Lowering Therapy

### Resource links provided by NLM:

MedlinePlus related topics: [Triglycerides](#)

[U.S. FDA Resources](#)

### Further study details as provided by Medical Research Laboratories International:

Estimated Enrollment: 50

Study Start Date: October 2004

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 diagnosis of Fredrickson Type I or V HTG
- be stable on current maximum tolerated triglyceride lowering therapy
- have a fasting TG level of at least 880 mg/dL (10 mmol/L)

- be male or nonpregnant, nonbreastfeeding female. The women in the study must be surgically sterile, postmenopausal or must practice an effective method of birth control
- must be able to give informed consent or if under the age of 18, parents or legal guardians must give their informed consent
- meet body weight requirements

**Exclusion Criteria:**

- Recent heart attack, coronary artery intervention, coronary bypass surgery, or stroke.
- Patients with class 3 or 4 heart failure
- Uncontrolled hypothyroidism or other uncontrolled endocrine disease
- Known, clinically significant eye abnormalities, such as cataracts
- History of hepatic disease or AST or ALT levels greater than 1.5 x ULN at Visit 1
- Alkaline phosphatase greater than 2 times ULN
- Serum creatinine greater than 2.0 mg/dL
- Liver cirrhosis and severe liver steatosis
- Clinically significant infection, malignancy, or psychosis
- Use of oral anticoagulants or digoxin unless the dose is stable and is regularly monitored
- Participation in any other investigational study within the last 30 days
- Breastfeeding or pregnant
- Current drug or alcohol abuse
- Serious or unstable medical conditions that would compromise the patient's safety or successful participation in the study
- Unwillingness to comply with study procedures or unwillingness to cooperate fully

► **Contacts and Locations**

Please refer to this study by its ClinicalTrials.gov identifier: NCT00080132

**Locations**

**United States, Ohio**

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

**United States, Texas**

The Methodist Hospital  
Houston, Texas, United States, 77030

**Netherlands**

Academic Medical Center Amsterdam  
Amsterdam, Netherlands, 1105 AZ

Andromed Noord  
Groningen, Netherlands, 9711 SG

Andromed Leiden  
Leiden, Netherlands, 2311 GZ

Andromed Rotterdam  
Rotterdam, Netherlands, 3021 HC

Andromed Oost  
Velp, Netherlands, 6883 HM

Andromed Zoetermeer  
Zoetermeer, Netherlands, 2724 EK

**Norway**

Lipidklinikken - Rikshospitalet  
Oslo, Norway

**Sponsors and Collaborators**

Medical Research Laboratories International

► **More Information**

No publications provided

ClinicalTrials.gov Identifier: [NCT00080132](#) [History of Changes](#)  
Other Study ID Numbers: MRL 2002-003  
Study First Received: March 23, 2004  
Last Updated: June 23, 2005  
Health Authority: United States: Food and Drug Administration

Keywords provided by Medical Research Laboratories International:

HTG

Hypertriglyceridemia, Fredrickson Type I

Hypertriglyceridemia, Fredrickson Type V

Additional relevant MeSH terms:

Hypertriglyceridemia

Hyperlipidemias

Dyslipidemias

Lipid Metabolism Disorders

Metabolic Diseases

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