4

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Trial record **1 of 3** for: implitapide

Previous Study | Return to List | Next Study

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

This study has been terminated.

Sponsor:
Medical Research Laboratories International

Information provided by:
Medical Research Laboratories International

ClinicalTrials.gov Identifier:
NCT00080132

First received: March 23, 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** 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: **implitapide**	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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