Lipid Treatment Assessment Project2

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Ethical reviewApproved WMOStatusRecruitment stoppedHealth condition typeCoronary artery disordersStudy typeObservational invasive

Summary

ID

NL-OMON29733

Source

ToetsingOnline

Brief title

NRA5090005/ L-TAP2

Condition

- Coronary artery disorders
- Endocrine and glandular disorders NEC

Synonym

dyslipidemia; increased cholesterol

Research involving

Human

Sponsors and support

Primary sponsor: Pfizer

Source(s) of monetary or material Support: de sponsor

Intervention

Keyword: Dyslipidemia, lipid managment, Treated

Outcome measures

Primary outcome

Eveluation of the concentration of LDL-C, HDL-C, totaal cholesterol and

triglyceride in treated dyslipidemic patients in the US, Canada, Mexico,

Brazil, Netherlands, France, Spain, Taiwan and Korea.

Secondary outcome

see page 3 and 4 of the protocol

Study description

Background summary

Epidemiologic data clearly demonstrate that risk of coronary heart disease is directly correlated with levels of LDL cholesterol (LDL-C) and inversely correlated with levels of HDL cholesterol (HDL-C)

During treatment of dylipidemia patients the main goal is to achieve the LDL-C values as described in the cholesterol management guidelines in order to decrease the cardiovascular risk.

Little is known about physicians* adherence to cholesterol management guidelines in daily practice.

The first L-TAP study showed that only 38% of the treated patients achieved the LDL-C goal

Study objective

While this survey will provide information about mean LDL-C levels and the percent of patients at LDL-C goals, the survey will also focus on HDL-C. A primary objective of this survey is to assess the levels of HDL-C in treated dyslipidemic patients, including patients attaining LDL-C treatment goals. This will improve our understanding of the residual cardiovascular risk remaining in patients treated with modern lipid modifying regimens by virtue of measuring HDL-C levels in a large and geographically divers sample.

Study design

Patients will visit the hospital/ General physician just one visit. During this visit Informed Consent will be documented, bloodpressure measurement will be done, weight will be recorded and waist circumference will be measured.

A blood sample will be taken, that will be analysed by a central lab.

All gathered data will be recorded in a Case Report Form.

Study burden and risks

The burden of the patients exists in a hospital visit where a bloodsample will be taken. The risk will be the possibility of suffusion on the punture place.

Contacts

Public

Pfizer

Rivium Westlaan 142 2909 LD Capelle a/d IJssel Nederland

Scientific

Pfizer

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years) Elderly (65 years and older)

Inclusion criteria

Exclusion criteria

recent trauma/ surgery; recent hospitalisation; acute infection which recuired anti-biotic treatment; pregnancy/ breastfeeding; myocardial infarction in the past 12 weeks.

Study design

Design

Study type: Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Treatment

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 11-01-2007

Enrollment: 1000

Type: Actual

Ethics review

Approved WMO

Date: 21-12-2006

Application type: First submission

Review commission: METC Maxima Medisch Centrum (Veldhoven)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register ID

CCMO NL13214.015.06