Lipid Treatment Assessment Project2

Published: 21-12-2006
Last updated: 20-05-2024

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...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Coronary artery disorders
Study type	Observational 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

Rivium Westlaan 142
2909 LD Capelle a/d IJssel
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients older than 20 years of age

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