Erythrocyte-bound apolipoprotein B after withdrawal of statin therapy

Published: 27-03-2012
Last updated: 28-04-2024

The aim of the study is to investigate the effect of statins on ery-apoB levels.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON38118

Source
ToetsingOnline

Brief title
EBABAST

Condition

- Other condition
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
Hypercholesterolemia

Health condition

hypercholesterolemie

Research involving
Human

Sponsors and support

Primary sponsor: Sint Franciscus Gasthuis
Source(s) of monetary or material Support: Stichting Onderzoek & Ontwikkeling Interne

specialismen (Sint Franciscus Gasthuis)

Intervention

Keyword: Apolipoprotein B, Erythrocyte, Statin

Outcome measures

Primary outcome

Erythrocyte-bound apolipoprotein B before and after discontinuation of statin

therapy.

Secondary outcome

none

Study description

Background summary

Preliminary data has shown that erythrocyte-bound apolipoprotein B (ery-apoB) has a protective effect on atherosclerosis. Moreover, a modest but significant negative correlation existed between ery-apoB and plasma apoB and LDL-C in subjects without statins but not in subjects with statins. The direct effects of statins on ery-apoB are unknown.

Study objective

The aim of the study is to investigate the effect of statins on ery-apoB levels.

Study design

A non-randomized intervention study. Ery-apoB will be measured twice in volunteers who are on statin therapy for medical reasons. After a baseline measurement of ery-apoB volunteers will discontinue their statin use for a period of six weeks followed by a second measurement of ery-apoB. Consecutively subjects will start with their original statin therapy again.

Intervention

Temporary discontinuation of statin therapy for a period of six weeks.

Study burden and risks

Volunteers will visit the outpatient clinic twice, the second visit will be exactly six weeks after the first visit. The volunteers* general practitioner and medical specialist (internist or cardiologist) will be informed about their participation. Subjects have to fast for 10 hours before every visit and venous blood samples will be drawn on both visits (a total of 36ml of blood). Subjects will discontinue their usual statin therapy for a period of three weeks. No major risks are involved with temporary discontinuation of statin therapy in stable chronic cardiovascular disease. Volunteers will receive 25 euros for participation. Subjects can be informed concerning their lipid profile and efficacy of their current statin use. Participation serves to further investigate the relation of statins and potentially beneficial binding of apoB on erythrocytes.

Contacts

Public
Sint Franciscus Gasthuis

Postbus 10900
3004 BA, Rotterdam
NL
Scientific
Sint Franciscus Gasthuis

Postbus 10900
3004 BA, Rotterdam
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Aged 18 years or older
Use of statin therapy

Exclusion criteria

A cardiovascular event (myocardial infarction, percutaneous coronary intervention or stroke) in the past 6 months.
The use of any other lipid lowering drugs besides a statin, for example ezetimibe or a fibrate in the past 6 months.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-07-2012
Enrollment:	53
Type:	Actual

Ethics review

Approved WMO

Date:	27-03-2012
Application type:	First submission
Review commission:	TWOR: Toetsingscommissie Wetenschappelijk Onderzoek

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	NL37698.101.11