

Effects of various doses of statin therapy on the endothelial function in young adults with familial hypercholesterolemia

Submission date

14/02/2006

Recruitment status

No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date

14/02/2006

Overall study status

Completed

☐ Statistical analysis plan

☐ Results

Last Edited

06/07/2009

Condition category

Nutritional, Metabolic, Endocrine

☐ Individual participant data

☐ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number

<http://www.trialregister.nl/trialreg/admin/rctview.asp?TC=532>

Study information

Scientific Title

A double blind cross-over trial to evaluate the effects of 5-40 mg/day simvastatin therapy on the endothelial function in young adults with familial hypercholesterolemia.

Acronym

EVALUATE

Study objectives

A threshold reduction in low density lipoprotein cholesterol (LDL-C) is required to improve endothelial function as measured by the flow mediated dilation (FMD).

Ethics approval required

Old ethics approval format

Ethics approval(s)

Received from local medical ethics committee

Primary study design

Interventional

Study design

Randomised, double blind, placebo controlled, crossover group trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Familial hypercholesterolemia (FH)

Interventions

Various doses of simvastatin (0-5-10-20-40 mg/day during 8 weeks), compared to placebo.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

simvastatin

Primary outcome(s)

The effect of various doses of simvastatin (5-40 mg) on endothelial function as measured by flow mediated dilatation (FMD) compared to placebo.

Key secondary outcome(s)

The cholesterol lowering effect of the various dosages of simvastatin compared to placebo.

Completion date

31/01/2008

Eligibility

Key inclusion criteria

Healthy heterozygous FH patients aged >18 years with a documented LDL receptor mutation and LDL cholesterol level above the 95th percentile for age and gender. Or LDL cholesterol above 95th percentile and a positive family history for FH or premature CAD.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

1. Females who are pregnant or intend to become pregnant
2. Hypersensitivity or contraindication to simvastatin
3. Excessive alcohol consumption, smoking or drug abuse

Date of first enrolment

01/02/2006

Date of final enrolment

31/01/2008

Locations

Countries of recruitment

Netherlands

Study participating centre

Academic Medical Center

Amsterdam

Netherlands

1100 DD

Sponsor information

Organisation

Academic Medical Center (Netherlands)

ROR

<https://ror.org/03t4gr691>

Funder(s)**Funder type**

Hospital/treatment centre

Funder Name

Academic Medical Center (Netherlands)

Alternative Name(s)

Academic Medical Center, Centre Médical Académique, ACADEMISCH MEDISCH CENTRUM AMSTERDAM, Academic Medical Center (Amsterdam), AMC

Funding Body Type

Government organisation

Funding Body Subtype

Universities (academic only)

Location

Netherlands

Results and Publications**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration