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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 [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 14/02/2006	**Overall study status** Completed	
Last Edited 06/07/2009	**Condition category** Nutritional, Metabolic, Endocrine	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Randomised, double blind, placebo controlled, crossover group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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

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

Overall study start date
01/02/2006

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
40

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)

Sponsor details
Department of Vascular Medicine
Meibergdreef 9
Amsterdam
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1105 AZ

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/03t4gr691

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Academic Medical Center (Netherlands)

Alternative Name(s)
Academic Medical Center, AMC

Funding Body Type
Private sector organisation

Funding Body Subtype

Universities (academic only)

Location
Netherlands

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration