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

No registrations found.

| | |
|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Pending |
| **Health condition type** | - |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON23698

**Source**
Nationaal Trial Register

**Brief title**
EVALUATE

### Sponsors and support

**Primary sponsor:** -
**Source(s) of monetary or material Support:** -

### Intervention

### Outcome measures

#### Primary outcome

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

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

# Study description

### Background summary

In 40 young adults with FH we will examine the effect of various dosis simvastatin (0-5-10-20-40 mg/day during 8 weeks) on the endothelial function. This will reveal whether a threshold exists for an LDL-C reduction required to improve FMD.

### Study objective

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

### Intervention

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

# Contacts

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# Eligibility criteria

## 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 95st percentile and a positive family history for FH or premature CAD.

## Exclusion criteria

Females who are pregnant or intend to become pregnant; hypersensitivity or contraidication to simvastatin; excessive alcohol consumption, smoking or drug abuse.

# Study design

## Design

| | |
|---|---|
| Study type: | Interventional |
| Intervention model: | Crossover |
| Masking: | Double blinded (masking used) |
| Control: | Placebo |

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Pending |
| Start date (anticipated): | 01-02-2006 |
| Enrollment: | 40 |
| Type: | Anticipated |

# Ethics review

Positive opinion

| | |
|---|---|
| Date: | 23-11-2005 |
| Application type: | First submission |

# 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 |
|---|---|
| NTR-new | NL490 |
| NTR-old | NTR532 |
| Other | : N/A |
| ISRCTN | ISRCTN47683043 |

# Study results

**Summary results**
N/A