Plaque reversal with Early, Aggressive Lipid Lowering

Published: 02-02-2021
Last updated: 08-04-2024

To determine whether plaques in young patients with familial hypercholesterolemia (aged below 50 years) are susceptible to significant plaque regression with early, aggressive lipid lowering therapy (statins, ezetimibe and/or PCSK9) according to...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Coronary artery disorders
Study type	Observational invasive

Summary

ID

NL-OMON49626

Source
ToetsingOnline

Brief title
EAGLE

Condition

- Coronary artery disorders
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
atherosclerosis

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: familial hypercholesterolemia, lipid lowering, plaque reversal

Outcome measures

Primary outcome

The main parameter to study will be the mean plaque progression (absolute

difference in total plaque volume between the initial and follow-up CCTA scan).

Secondary outcome

The secondary study parameters to be studied will be the following:

• Relative mean plaque progression

• Number of high-risk plaque features, i.e.:

o positive remodelling (RI>1.1)

o low attenuation plaque (<= 30 HU)

o spotty calcification

o napkin ring sign

• Difference in non-calcified plaque volume between baseline and follow-up CCTA

(delta non-calcified plaque volume)

• Difference in calcified plaque volume between baseline and follow-up CCTA

(delta calcified plaque volume)

• Difference in fat attenuation index (FAI) between initial and follow-up CCTA

scan

• Lipid parameters

Study description

Background summary

It is believed that early (at a young age) aggressive lipid lowering treatment can reverse atherosclerotic plaque formation and sometimes cure atherosclerosis, in contrast to the inability of plaques to regress in older patients. We recently substantiated this concept by a case series of two adolescent null/null homozygous familial hypercholesterolemia (FH) patients who showed an unprecedented ~80% plaque reduction after aggressive lipid lowering therapy with statins, ezetimibe, LDL apheresis, enforced with PCSK9 inhibition.

Study objective

To determine whether plaques in young patients with familial hypercholesterolemia (aged below 50 years) are susceptible to significant plaque regression with early, aggressive lipid lowering therapy (statins, ezetimibe and/or PCSK9) according to clinical guidelines.

Study design

Serial CCTA imaging before and 30-40 weeks after aggressive lipid lowering therapy.

Study burden and risks

Participating subjects in this study receive no direct clinical benefits from participation in this study, except for optimalization of their LDL cholesterol lowering regimen according to current clinical practice/guidelines. The burden and risk of participating in this study is estimated to be low. The study requires three visits. Blood withdrawal for clinical laboratory assessment will be limited to 41.5 ml. Patients will be exposed to a limited radiation burden related to CCTA imaging (2.8 mSv). Furthermore, there is a very small risk of contrast nephropathy.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105AZ
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Diagnosed with heterozygous familial hypercholesterolemia
- Adult between 18 and 50 years old
- LDL cholesterol levels above 100 mg/dl (>2.6 mmol/L) at inclusion

Exclusion criteria

- Renal insufficiency, defined as eGFR < 30 ml/min
- History of atherosclerotic cardiovascular events
- Atrial fibrillation
- Any other treatment or clinically relevant condition that could interfere with the conduct or interpretation of the study in the opinion of the investigator
- Inability or unwillingness to comply with the protocol requirements, or deemed by investigator to be unfit for the study

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	30-07-2021
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO

Date:	02-02-2021
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL75337.018.20