Coronary and Heart Effects of Early Treatment in Familial Hypercholesterolemia

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To evaluate plaque burden and characteristics in early-treated FH patients and to compare coronary plaque burden and characteristics between early- and late-treated FH patients as well as with non-FH controls.

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

Summary

ID

NL-OMON51451

Source
ToetsingOnline

Brief title
CHEETAH

Condition

- Coronary artery disorders

Synonym
familial hypercholesterolemia

Research involving
Human

Sponsors and support

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

Intervention

Keyword: CCTA, familial hypercholesterolemia

Outcome measures

Primary outcome

The main parameter to study will be the total coronary plaque volume.

Secondary outcome

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

• Presence of obstructive stenosis (and number of vessels)

• Presence of any stenosis (and number of vessels)

• Calcified plaque volume

• Non-calcified plaque volume

• Number and presence 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

• Fat attenuation index (FAI)

• Lipid parameters

Study description

Background summary

It has been shown that early lipid lowering treatment in familial hypercholesterolemia (FH) patients reduces CVD events at the mean age of 32. It is not known what the effect of early treatment is on coronary plaque burden in

these patients.

Study objective

To evaluate plaque burden and characteristics in early-treated FH patients and to compare coronary plaque burden and characteristics between early- and late-treated FH patients as well as with non-FH controls.

Study design

Single center, observational, cross-sectional study.

Study burden and risks

The results of this study contribute to the understanding of the effects of early statin-treatment in FH patients. It is not known whether these patients will experience CVD events at a later age and how this early treatment affects coronary plaque development.

Participating FH patients or non-FH controls in this study receive no direct clinical benefits from clinical CCTA imaging. However, the expected risk for participants is low. The most important risk in this study is radiation exposure. However, the maximum exposure related to CCTA imaging is 1.4 mSv. This a low radiation exposure and is lower than the yearly dose of background radiation in the Netherlands. Furthermore, ionized contrast agents will be used during CCTA, which can be nephrotoxic and may elicit allergic reactions. In addition, incidental extra-coronary findings, such as pulmonary malignancies, can be a potential benefit from CCTA imaging since early detection of these findings may enable early treatment. Cardiac findings, such as significant coronary lesions, will be left at the discretion of the treating physician.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- Diagnosed with heterozygous familial hypercholesterolemia or non-FH control
- Adult patients between 25 and 55 years old

Exclusion criteria

- Renal insufficiency, defined as eGFR < 30 ml/min
- 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
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-03-2022
Enrollment:	144
Type:	Actual

Ethics review

Approved WMO Date:	01-02-2022
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	29-03-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	01-08-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	31-10-2022
Application type:	Amendment
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	NL79640.018.21

Study results

Date completed: 19-12-2022

Actual enrolment: 135

Summary results
Trial is onging in other countries