Effect of prolonged cholesterol lowering treatment on trained immunity of monocytes in patients with elevated levels of LDL-cholesterol

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Arteriosclerosis, stenosis, vascular insufficiency and necrosis
Study type	Observational non invasive

Summary

ID

NL-OMON49515

Source
ToetsingOnline

Brief title
Prolonged cholesterol lowering and TRIM

Condition

- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
Cardiovascular disease, hypercholesterolemia

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum

Source(s) of monetary or material Support: Nederlands Hart Stichting

Intervention

Keyword: Cardiovascular Diseases, Familial Hypercholesterolemia, Inflammation, Innate Immunity

Outcome measures

Primary outcome

In this study we want to evaluate the long term effect of cholesterol lowering

treatment (1year) on the circulating innate immune cell in patietns with

familial hypercholesterolemia. This most important question is if long term

treatment can effect the trained immunity phenotype.

Secondary outcome

nvt

Study description

Background summary

Cardiovascular disease accounts for more than 2.5 million deaths each year. Previous research has shown the prominent role of white bloodcells, that form a part of our immune system, in cardiovascular disease. These cells are prone for inflammation which promotes atherosclerosis.

Study objective

Since high cholesterol is a major riskfactor for cardiovascular disease we will select patients with inhirated elevated cholesterol (familial hypercholesterolemia. We want to evaluate the long term effect of cholesterol lowering treatment on the increased pro inflammatory response by their white blood cells.

Study design

This is an observationeel multi center study

Study burden and risks

There is no direct benefit to the study participants. The risks for participants are overall negligible, except for possible discomfort related to the venepuncture. After signing for informed consent, blood will be drawn, followed by 3months and 12 months timepoint.
The healthy volunteers will only have one time point blooddraw at the beginning of the study.
The blooddraw doesn*t impose a risk for the participants, other than a possible hematoma at the puncture site.

Contacts

Public
Radboud Universitair Medisch Centrum

Geert Grooteplein Zuid 8
Nijmegen 6525 GA
NL
Scientific
Radboud Universitair Medisch Centrum

Geert Grooteplein Zuid 8
Nijmegen 6525 GA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients:
- Aged 18 years or older
- They are eligible for participation if they fulfil the criteria for *possible* FH (3-5 points), *probable* FH (6-8 points) or *definitive* FH (>8 points), according to the Dutch Lipid Clinic Network diagnostic criteria for familial hypercholesterolemia and untreated LDL levels >4.9 mmol/l and requiring lipid lowering treatment according to the treating physician
- No previous cardiovascular events
- Written informed consent

Control subjects:
- Age 18 years or older
- LDL cholesterol <3.5 mmol/l
- No previous cardiovascular events
- Written informed consent

Exclusion criteria

- Current lipid lowering treatment or treatment with lipid lowering drugs in the past year.
- Age <18 years
- Inability to personally provide written informed consent (e.g. for linguistic or mental reasons)
- Current treatment for maliganancy
- Acute or chronic infections with fever at the time of participation
- Medical history of any disease associated with immune deficiency (either congenital or acquired, including chemotherapy, chronic steroid use, organ transplant)
- Clinically significant infections within 1 months prior to study entry (defined as fever >38.5)
- Previous vaccination within 1 months prior to study entry
- Chronic use of anti-inflammatory drugs such as NSAIDs (acetylsalicylic acid <100 mg/day excluded

Study design

Design

Study type:	Observational non invasive

Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-12-2020
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	13-10-2020
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL72155.091.20