Antigen specific T cells in advanced human atherosclerosis

Published: 24-02-2020
Last updated: 12-04-2024

The primary objective of this study is to measure the number of antigen specific T-cells in the plaque and in blood, and investigate whether these parameters correlate with the phenotype of the atherosclerotic plaque. Secondary objectives are: 1) To...

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

Summary

ID

NL-OMON56159

Source
ToetsingOnline

Brief title
Antigen-specific T cells in atherosclerosis

Condition

- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
arterial stenosis, atherosclerosis

Research involving
Human

Sponsors and support

Primary sponsor: Haaglanden Medisch Centrum
Source(s) of monetary or material Support: deze studie wordt gefincancierd door de Hartstichting (ontvanger: BioTherapeutics van het LACDR/Universiteit Leiden)

Intervention

Keyword: atherosclerosis, blood vessels, endarterectomy, T-cell

Outcome measures

Primary outcome

The primary objective of this study is to measure the number of antigen specific T-cells in the plaque and in blood, and investigate whether these parameters correlate with the phenotype of the atherosclerotic plaque.

Secondary outcome

Secondary objectives are: 1) To investigate the inflammatory status of other immune cells (dendritic cells, macrophages, mast cells, etc) in atherosclerosis by flow cytometry and gene expression analysis. 2) To correlate plaque phenotype to CT-angiography plaque characteristics. 3) To investigate whether gender has an effect on these T-cells and other immune cell subsets and plaque phenotype.

Study description

Background summary

Atherosclerosis is the primary cause of major adverse cardiovascular events (MACE), including myocardial infarction (MI) and stroke. It is characterized by lipid accumulation and inflammation in middle and large-sized arteries. T-cells play an important role in the propagation of inflammation inside the lesion. Moreover, these cells have been shown to actively contribute to plaque destabilization. Elevated numbers of T-cells in blood have been shown to correlate with MACE. Although these are encouraging results, these analyses are compromised by the presence of T-cells that are not derived from the atherosclerotic lesions and are not involved in mediating inflammation in the atherosclerotic lesion, thereby decreasing their prognostic value. We hypothesize that determining the number of T-cells that are specifically associated with atherosclerosis will provide a more accurate and robust

prediction of plaque phenotype and potential instability. Previous studies investigating mouse and human atherosclerosis suggest T-cells may react towards the proteinous components of LDL (the ApoB100 protein). T-cells reactive to the antigen ApoB100 may play an important role in progression of atherosclerosis and the number and/or activation state of these T-cells in blood may reflect the stage of atherosclerosis.

Study objective

The primary objective of this study is to measure the number of antigen specific T-cells in the plaque and in blood, and investigate whether these parameters correlate with the phenotype of the atherosclerotic plaque. Secondary objectives are: 1) To investigate the inflammatory status of other immune cells (dendritic cells, macrophages, mast cells etc) in atherosclerosis. 2) To correlate plaque phenotype to CT-angiography plaque characteristics. 3) To investigate whether gender has an effect on these T-cells, other immune cell subsets and plaque phenotype.

Study design

Observational study.

Study burden and risks

There will be no additional risk involved for patients, since this study makes use of waste material harvested during the operation. The extra required blood sample will be taken prior to surgery via vena punction (and prior to general anaesthesia).

Contacts

Public
Haaglanden Medisch Centrum

Lijnbaan 32
Den Haag 2512 VA
NL
Scientific
Haaglanden Medisch Centrum

Lijnbaan 32
Den Haag 2512 VA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
- Patients undergoing endarterectomy surgery
- Patients who are older than 18 years
- Patients able to give their consent to enter the study
- Patients who have signed an informed consent and the agreement form.

Exclusion criteria

- Patients younger than 18 years old
- Patients who are not able to give their consent to enter the study
- Patients who have not signed an informed consent and the agreement form.
- Patients that have already had an endarterectomy previously and are undergoing a redo of this surgery.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	04-06-2020
Enrollment:	200
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	24-02-2020
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	21-12-2023
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL71516.058.19