

# Mast cell activation in stable versus unstable human atherosclerotic plaques

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The main objective is to investigate whether local mast cell activation correlates with an unstable phenotype of the atherosclerotic plaque. Secondary objectives are: 1. To investigate whether elevated systemic mast cell markers are correlated to...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Completed
<b>Health condition type</b>	Vascular therapeutic procedures
<b>Study type</b>	Observational invasive

## Summary

### ID

NL-OMON46044

### Source

ToetsingOnline

### Brief title

Mast cell activation in atherosclerosis

### Condition

- Vascular therapeutic procedures
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

### Synonym

atherosclerosis, carotid artery stenosis

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Heelkunde

**Source(s) of monetary or material Support:** Kosten voor dit onderzoek wordt gedragen door de afdeling Biofarmacie van de Universiteit Leiden (wis- en natuurkunde faculteit)

## Intervention

**Keyword:** Atherosclerosis, Immune cells, Mast cells, Plaque stability

## Outcome measures

### Primary outcome

The main study parameter is the percentage of mast cell activation in stable versus unstable atherosclerotic plaques.

### Secondary outcome

1. To investigate whether elevated systemic mast cell markers are correlated to the stability of the atherosclerotic plaque. 2. To investigate correlation of allergies or lung disease with local and systemic mast cell activation in atherosclerosis 3. To investigate the inflammatory status of other immune cells (dendritic cells, macrophages, etc) in atherosclerosis. 4. To investigate whether gender has an effect on immune cell subsets and plaque stability.

## Study description

### Background summary

Unstable atherosclerotic plaques may rupture, which can lead to thrombosis with subsequent ischemic events such as a cerebral infarction. Preclinical research has pointed out that the mast cell, a potent immune cell, plays a major role in the destabilization of atherosclerotic plaques. Up to now, the cellular composition of human atherosclerotic plaques has been investigated with immunohistochemistry and rt-PCR. Recently we have developed a novel method to determine immune cell subsets in atherosclerotic plaques by means of flow cytometry. This technique does not only allow us to analyse the cellular contents of the human atherosclerotic plaque, but also to investigate the gene expression of each unique cell type in the plaque, rather than looking at the gene expression of all the cells together. This will give us unique new insights into the composition of immune cells, specifically the mast cell, in the atherosclerotic plaque.

Additional emphasis will be placed on the difference of the atherosclerotic

plaque composition in men versus women. This is of high social relevance and a particular area of interest for both the \*Nederlandse Hartstichting\* (<https://www.hartstichting.nl/vrouwen>) and the NWO (program Gender and Health: <http://www.zonmw.nl/nl/programmas/programma-detail/gender-en-gezondheid/algemeen/>)

## **Study objective**

The main objective is to investigate whether local mast cell activation correlates with an unstable phenotype of the atherosclerotic plaque.

Secondary objectives are: 1. To investigate whether elevated systemic mast cell markers are correlated to mast cell content in the atherosclerotic plaque. 2. To investigate whether allergies or lung diseases associate with local and systemic mast cell parameters in atherosclerosis 3. To investigate the inflammatory status of other immune cells (dendritic cells, macrophages, etc) in atherosclerosis 4. To investigate whether gender has an effect on immune cell subsets and plaque stability.

## **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 during surgery via vena-puncture

## **Contacts**

### **Public**

Selecteer

Bronovolaan 5  
Den Haag 2597 AX  
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### **Scientific**

Selecteer

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Den Haag 2597 AX  
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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

Patients undergoing endarterectomy surgery and who are older than 18 years; able to give their consent to enter the study and 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 agreement form

## Study design

### Design

**Study type:** Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Other

### Recruitment

NL

Recruitment status: Completed

Start date (anticipated):	01-11-2017
Enrollment:	50
Type:	Actual

## Ethics review

Approved WMO	
Date:	31-08-2017
Application type:	First submission
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	NL57482.098.17

## Study results

Date completed:	06-01-2019
Results posted:	08-01-2020

**First publication**  
01-01-1900