

# The role of inflammation in myocardial infarction in young patients without cardiovascular risk factors: the "unhappy few" - a pilot study -

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To investigate the innate pro-inflammatory response in young patients (

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

## Summary

### ID

NL-OMON46159

### Source

ToetsingOnline

### Brief title

the unhappy few

### Condition

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

### Synonym

heart attack, myocardial infarction

### Research involving

Human

### Sponsors and support

**Primary sponsor:** RadboudUMC

**Source(s) of monetary or material Support:** voorlopig worden de kosten betaald uit de

financiële reserves van de afdeling cardiologie;

## Intervention

**Keyword:** acute myocardial infarction, inflammatie, trained immunity

## Outcome measures

### Primary outcome

Peripheral blood samples will be drawn for isolation of monocytes and thrombocytes. The primary endpoint are histone marks of chromatin accessibility such as H3K4 trimethylation (H3K4me3) and H3K9me2 in the promoter region of inflammatory cytokines

### Secondary outcome

Secondary endpoints are the cytokine release by monocytes in response to stimulation with Toll-like Receptor(TLR)-agonists and the transformation of monocytes in foam cells. Also the specific blood platelet function in these patients will be examined.

## Study description

### Background summary

A number of patients suffers from an acute myocardial infarction (AMI) despite the absence of the \*classical\* risk factors for atherosclerosis; we consider them to be the \*unhappy few\*. Numerous studies have shown that atherosclerosis is a chronic inflammatory disease and we hypothesize that these \*unhappy few\* have an (epi-)genetic predisposition of an exaggerated innate pro-inflammatory response, which accelerates the process of atherosclerosis.

### Study objective

To investigate the innate pro-inflammatory response in young patients (<50 years of age), who suffered from a myocardial infarction. The pro-inflammatory response will be examined by the search for immunological and epigenetic

signature characterizing \*trained immunity\* especially in the monocytes of peripheral blood, which leads to a more vigorous reaction and to more production of pro-inflammatory cytokines. At the same time the function of platelets in peripheral blood will be examined, as platelets form part of the inflammatory response.

## **Study design**

single-center, observational study

## **Study burden and risks**

In the patients 4 tubes of peripheral blood will be taken prior to and after one week of statin treatment interruption. Fourteen days of interruption of statin treatment in stable patients more than 1 year after their myocardial infarction is not expected to result in worse clinical outcome. Additionally, fourteen days of aspirin therapy in healthy controls is not expected to result in adverse clinical outcome.

## **Contacts**

### **Public**

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## **Trial sites**

### **Listed location countries**

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

Cases: 20 patients aged between 18 and 50 year, who presented 1-4 years ago with an acute ST-elevation myocardial infarction without classic cardiovascular risk factors.;controls: 20 healthy controls aged 18 or above. controls will be matched with the cases for age, gender and cardiovascular risk factors.

### Exclusion criteria

patients:

- If the index patient has:

- o Coagulation disorder

- o Diagnosis of vascular disease (e.g. previous myocardial infarction, CVA, etc)

- o If the index patient has two or more of the following factors present:Hypertension

- o Hypercholesterolemia

- o Diabetes mellitus

Active smoking or an active smoking history within the last 10 years;controles:

- o Coagulation disorder

- o Diagnosis of vascular disease (e.g. previous myocardial infarction, CVA, etc)

- o If the index patient has two or more of the following factors present:Hypertension

- o Hypercholesterolemia

- o Diabetes mellitus

Active smoking or an active smoking history within the last 10 years

## 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): 20-04-2018

Enrollment: 40

Type: Actual

## Ethics review

Approved WMO

Date: 11-09-2017

Application type: First submission

Review commission: CMO regio Arnhem-Nijmegen (Nijmegen)

Approved WMO

Date: 12-06-2018

Application type: Amendment

Review commission: CMO regio Arnhem-Nijmegen (Nijmegen)

Approved WMO

Date: 21-10-2019

Application type: Amendment

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

CCMO

### ID

NL61543.091.17