

# Visualisation of disease progression in human coronary arteries and the relationship with biomechanical forces

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<b>Registration date</b> 07/07/2020	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 07/08/2020	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

A myocardial infarction (MI), also known as a heart attack, occurs when blood flow decreases or stops to a part of the heart, causing damage to the heart muscle. Atherosclerosis is a disease in which plaque builds up inside the arteries. Arteries are blood vessels that carry oxygen-rich blood to the heart and other parts of the body. Plaque is made up of fat, cholesterol, calcium, and other substances found in the blood. Over time, plaque hardens and narrows the arteries. Acute coronary syndrome is a term used to describe a range of conditions associated with sudden, reduced blood flow to the heart.

The aim of this study is to investigate the association between shear stress and plaque growth and plaque composition changes over time in patients with acute coronary syndrome. Furthermore, the local stress inside the plaque will be calculated to investigate possible rupture risk.

### Who can participate?

Patients with acute coronary syndrome that are eligible for percutaneous coronary interventions and who contain arteries that are accessible with imaging catheters. Patients will need to give their informed consent.

### What does the study involve?

The study involves additional imaging of another non-treated, less severe diseased coronary artery during the percutaneous coronary intervention initiated for treatment of the most diseased coronary artery. After 1 year, imaging of the non-treated coronary artery is repeated during another percutaneous coronary intervention. During these interventions blood will be collected. Furthermore, one month after the initial procedure a computed tomography coronary angiogram is acquired. Besides, regular clinical check-ups are performed.

### What are the possible benefits and risks of participating?

Intravascular coronary imaging is often part of the clinical routine in percutaneous coronary intervention as it can help the operator to achieve an optimal stent result. The burden of this study to the patient at baseline and follow-up is the additional imaging of non-treated coronary,

which adds extra time to the total procedural time and a very small risk of coronary complications associated with introduction of a guide wire and imaging catheter in the coronary artery (less than 1 promille). The patient might potentially benefit from the invasive imaging in two ways. First, invasive imaging might help to reach optimal treatment of the most diseased region of the coronary artery and at follow up the treatment location will be investigated for restenosis, and if necessary re-treated. Secondly, thorough evaluation of the less severe diseased vessel might reveal additional, significant, but angiographically silent lesions warranting treatment. Recently the failure rate of angiography to visualize such additional lesions causing clinical events in the near future, has been

Where is the study run from?

The study will be run at the Thoraxcenter of the ErasmusMC Rotterdam, the Netherlands

When is the study starting and how long is it expected to run for?

August 2015 to April 2019

Who is funding the study?

The study is in part funded by the European Research Council

Who is the main contact?

Dr. ir. JJ Wentzel, [j.wentzel@erasmusmc.nl](mailto:j.wentzel@erasmusmc.nl)

## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

### EudraCT/CTIS number

Nil known

### IRAS number

### ClinicalTrials.gov number

Nil known

## **Secondary identifying numbers**

METC-2015-535

# **Study information**

## **Scientific Title**

Imaging and Modeling to investigate the mutual relationship of plaque growth and biomechanical parameters in human coronary arteries

## **Acronym**

IMPACT

## **Study objectives**

The objective of this study is to investigate the association between biomechanical parameters (e.g. shear stress) and plaque geometry and composition and plaque changes over time. This study has a large potential in finding new parameters that give novel insights in plaques that might cause a myocardial infarction. Thereby this study might contribute to the identification of patients at risk of cardiovascular events in the future.

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

Approved 05/11/2015, Medisch Ethische Toetsings Commissie of the ErasmusMC (Molewaterplein 50, Rotterdam, the Netherlands; no telephone number provided; metc@erasmusmc.nl), ref: METC-2015-535 Positief Besluit NL54519.078.15, v02

## **Study design**

Single-center prospective observational longitudinal- study

## **Primary study design**

Observational

## **Secondary study design**

Longitudinal study

## **Study setting(s)**

Hospital

## **Study type(s)**

Diagnostic

## **Participant information sheet**

Not available in web format, please use the contact details below to request a patient information sheet

## **Health condition(s) or problem(s) studied**

Acute coronary syndrome

## Interventions

This study is an observational study on atherosclerotic plaque progression in human coronary arteries. The aim of this study is to investigate the influence of biomechanical factors on plaque progression over time. The intravascular imaging of the coronary arteries that is performed at baseline and after one year follow up will be used to delineate the local atherosclerotic plaque thickness. By also analyzing the local plaque thickness at one year follow up the local plaque progression will be measured. Furthermore, biomechanical parameters will be calculated using finite element modelling using 3D reconstructions of the coronary arteries based on information from intravascular imaging and computed tomography. Moreover, plaque phenotype will be identified and used in further analysis.

### Methodology:

Acute coronary syndrome patients treated for coronary artery disease at the catheterization laboratory are enrolled in this study. After treatment of the most diseased coronary artery (indication for the percutaneous coronary intervention), another less severe diseased coronary artery is imaged using multiple imaging modalities and this imaging procedure is repeated at the catheterization laboratory after one year. Furthermore at one month after the first imaging moment, the patient will undergo a CT coronary angiography procedure. Blood is collected during the baseline and follow up imaging procedure.

## Intervention Type

Other

## Primary outcome measure

1. Shear stress measured using computational fluid dynamics in 3D reconstructions of the coronary arteries based on the imaging at baseline and categorized as low, mid or high at baseline and 1 year
2. Plaque geometry and composition (including wall thickness, cap thickness and lipids) measured at several locations in the coronary arteries using images acquired and compared for regions exposed to low, mid and high shear stress at baseline and 1 year

## Secondary outcome measures

Stress inside the wall will be calculated using finite element modelling based on the images acquired at baseline and 1 year follow up

## Overall study start date

05/08/2015

## Completion date

17/04/2019

## Eligibility

### Key inclusion criteria

1. Patient eligible for PCI of a native coronary artery
2. Written informed consent obtained
3. Study coronary artery must be accessible to the OCT /NIRS-IVUS catheters

## Participant type(s)

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

70

**Total final enrolment**

56

**Key exclusion criteria**

1. Unable to provide informed consent
2. Under 18 years of age
3. Hemodynamic instability
4. Cardiogenic shock
5. TIMI 0 flow at target lesion site
6. Lesion beyond acute bends or in a location within the coronary anatomy where the catheter cannot transverse
7. Bypass graft as target vessel
8. Ejection fraction less than 30%
9. Contra-indication to emergency coronary artery bypass surgery
10. No access to cardiac surgery
11. Contra-indication to treatment with aspirin, ticlopidine, clopidogrel, prasugrel, ticagrelor, or heparin
12. Renal insufficiency (creatinine clearing < 50ml/min)
13. Pregnancy or inadequate contraception
14. History of bleeding diathesis or coagulopathy.
15. History of stroke within the past year
16. History of significant gastrointestinal bleed within the past month

**Date of first enrolment**

03/03/2016

**Date of final enrolment**

30/03/2018

**Locations****Countries of recruitment**

Netherlands

**Study participating centre**

Erasmus University Medical Center  
Molewaterplein 50

Rotterdam  
Netherlands  
3000 CA

## Sponsor information

### Organisation

Erasmus University Medical Center

### Sponsor details

Molewaterplein 50  
Rotterdam  
Netherlands  
3000 CA  
+31 10 7033938  
f.zijlstra.1@erasmusmc.nl

### Sponsor type

University/education

### Website

<http://www.erasmusmc.nl/>

### ROR

<https://ror.org/018906e22>

## Funder(s)

### Funder type

Research council

### Funder Name

European Research Council

### Alternative Name(s)

ERC

### Funding Body Type

Government organisation

### Funding Body Subtype

National government

### Location

# Results and Publications

## Publication and dissemination plan

The outcome of the study will be published in scientific journals.

## Intention to publish date

01/08/2020

## Individual participant data (IPD) sharing plan

All data generated or analysed during this study will be included in the subsequent results publication.

## IPD sharing plan summary

Other

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol file</a>	version v2.0	08/11/2016	07/08/2020	No	No