# Earlier recognition of Aortic Dissection and Aneurysm Rupture: The RADAR study.

Published: 11-11-2019 Last updated: 09-04-2024

The current study aims to establish age-dependent and sex-specific normal values for novel imaging biomarkers using 4D flow MRI and CFD.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Aneurysms and artery dissections
Study type	Observational non invasive

# Summary

### ID

NL-OMON48056

**Source** ToetsingOnline

**Brief title** RADAR

## Condition

• Aneurysms and artery dissections

**Synonym** Aortic dilatation, Aortic rupture

**Research involving** Human

## **Sponsors and support**

**Primary sponsor:** Medisch Universitair Ziekenhuis Maastricht **Source(s) of monetary or material Support:** Ministerie van OC&W

### Intervention

**Keyword:** Aortic Aneurysm (MESH), Aortic Dissection (MESH), Aortic Rupture (MESH), Magnetic Resonance Imaging (MESH)

### **Outcome measures**

#### **Primary outcome**

Description and quantification of regional hemodynamic parameters, blood flow

patterns, mechanical and structural properties of the aortic vessel wall and

transmural blood pressure in the aorta.

#### Secondary outcome

N/A

# **Study description**

#### **Background summary**

The link between aortic aneurysm formation and the risk of acute complications (rupture or dissection) has been well-described. Clinical management of aneurysms is aimed at prevention of these complications by regular evaluation of the maximum aortic diameter. Prophylactic aortic surgery is recommended when aortic size exceeds diameter thresholds as defined in current clinical guidelines. However, the value of aortic size as predictor for acute aortic events is debated, as most dissection patients exhibit diameters below the cut-offs for preventative aortic surgery. Using 4-dimensional flow magnetic resonance imaging (4D flow MRI) and computational fluid dynamics (CFD) modelling, the current study aims to describe new imaging biomarkers (e.g. hemodynamical flow mapping, vessel wall mapping, and transmural blood pressure mapping), which can improve the identification of patients at risk for aortic dissection and rupture at an early stage.

#### **Study objective**

The current study aims to establish age-dependent and sex-specific normal values for novel imaging biomarkers using 4D flow MRI and CFD.

### Study design

This study is a multicentre observational study conducted at the Maastricht University Medical Center (MUMC+) and Leiden University Medical Center (LUMC).

### Study burden and risks

This is an observational study which has no therapeutic consequences. Flow MRI scan protocols are routinely used in clinical practice and thus non-experimental. Participants are not subject to ionizing radiation. No contrast agent will be administered during the 4D flow MRI scans. Study results will improve understanding of aneurysm formation and the occurrence of acute natural complications. This data may provide for a better selection of patients who will benefit from pre-emptive aortic surgery, and \* eventually \* to a decrease in the incidence of potentially fatal aortic dissection and rupture.

# Contacts

#### Public

Medisch Universitair Ziekenhuis Maastricht

P. Debyelaan 25 Maastricht 6229HX NL **Scientific** Medisch Universitair Ziekenhuis Maastricht

P. Debyelaan 25 Maastricht 6229HX NL

# **Trial sites**

# **Listed location countries**

Netherlands

# **Eligibility criteria**

#### Age

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

3 - Earlier recognition of Aortic Dissection and Aneurysm Rupture: The RADAR study. 11-05-2025

# **Inclusion criteria**

Age > 18 years old and <70 years old. Mentally competent. Informed written consent.

### **Exclusion criteria**

Atrial fibrillation or tachycardia >100 bpm. Hypertension (>140/90mmHg Known aortic disease (aorta aneurysma, connective tissue disease, dissection, or prior aortic surgery. Chest pain suggestive for symptomatic aneurysm or acute aortic syndrome. Contra-indication for MRI-examination

# Study design

### Design

Study type: Observational non invasive		
Masking:	Open (masking not used)	
Control:	Uncontrolled	
Primary purpose:	Prevention	

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	27-12-2019
Enrollment:	200
Туре:	Actual

# **Ethics review**

Approved WMO	
Date:	11-11-2019
Application type:	First submission

4 - Earlier recognition of Aortic Dissection and Aneurysm Rupture: The RADAR study. 11-05-2025

Review commission:

# **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 NL69521.068.19