

# CCS in RA subjects compared to Type 2 DM

Published: 27-08-2015

Last updated: 21-04-2024

Goal is to analyse if the extent of Coronary arterial calcification in RA versus type 2 DM patients is equal.

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

## Summary

### ID

NL-OMON42120

### Source

ToetsingOnline

### Brief title

CCS in RA versus Type 2 DM

## Condition

- Coronary artery disorders

### Synonym

Atherosclerosis, Coronary Athreosclerosis

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Sint Franciscus Gasthuis

**Source(s) of monetary or material Support:** Francis Study

## Intervention

**Keyword:** Coronary Calcium Score, Rheumatoid Arthritis, Type 2 Diabetes Mellitus

## Outcome measures

### Primary outcome

Coronaire Calcium score using the Agatston et. al 1990.

### Secondary outcome

Explorative study on Aortic valve calcification using Calcium score discribed by Agatston et. al 1990.

## Study description

### Background summary

Studies show that RA patients have a higher risk to develop cardiovascular diseases which causes atherosclerosis. This increase cardiovascular risk is also seen in type 2 DM patients; of which periodic testing of the blood pressure and laboratory tests such as cholesterol are being implemented. Studies show that strict prevention and therapy help reduce the risk of cardiovascular diseases. Three ways to measure the extent of atherosclerosis are ultrasound of the carotid arteries, a scan of the coronary arteries and the aortic valve to measure arterial - and valve calcification using calculation described by the Agatston et al 1990.

### Study objective

Goal is to analyse if the extent of Coronary arterial calcification in RA versus type 2 DM patients is equal.

### Study design

Cross sectional study with matched RA and type 2 DM population, comparing their the Coronary Calcium score.

### Study burden and risks

Patients need to visit the hospital to undergo the CT-scan, in which they will be exposed to a dose of radiation (equal to 2x dose of spinal X-ray).

## Contacts

### **Public**

Sint Franciscus Gasthuis

Kleiweg 500  
Rotterdam 3045PM  
NL

### **Scientific**

Sint Franciscus Gasthuis

Kleiweg 500  
Rotterdam 3045PM  
NL

## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### **Age**

Adults (18-64 years)

Elderly (65 years and older)

### **Inclusion criteria**

Inclusion criteria for RA patients:

- 1) 40-< 60 years old.
  - 2) Established RA according to the American College of Rheumatology 1987 Criteria [39];
  - 3) Participation in the FRANCIS study which implies the availability of at least one recent cIMT measurement.
  - 4) Written informed consent.;
- Inclusion criteria for type 2 DM patients
- 1) 40-< 60 years old;
  - 2) Diagnosis of Type 2 Diabetes Mellitus according to national and international guidelines [40, 41];
  - 3) Availability of at least one recent cIMT measurement;
  - 4) Written informed consent.

## Exclusion criteria

Exclusion criteria for RA:

- 1) RA patients with type 1 DM or Type 2 DM;
- 2) Severely decreased kidney function (MDRD under 30);
- 3) Cardiovascular event in history: cerebrovascular attack, acute myocardial infarction, CABG, PTCA and amputation, PTA or intermittent claudication due to peripheral artery disease. ;Exclusion criteria for DM type 2:

- 1) Presence of RA in Type 2 DM patients.
- 2) Severely decreased kidney function (MDRD under 30).
- 3) Cardiovascular event in history: cerebrovascular attack, acute myocardial infarction, CABG, PTCA and amputation, PTA or intermittent claudication due to peripheral artery disease.

## Study design

### Design

**Study type:** Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Basic science

### Recruitment

NL

Recruitment status: Pending

Start date (anticipated): 30-07-2014

Enrollment: 100

Type: Anticipated

## Ethics review

Approved WMO

Date: 27-08-2015

Application type: First submission

Review commission: TWOR: Toetsingscommissie Wetenschappelijk Onderzoek Rotterdam e.o. (Rotterdam)

## 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	NL49587.101.14