# Assessment of endothelial dysfunction and premature atherosclerosis in patients with recent onset Rheumatoid Arthritis, a longitudinal study

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In this investigation we want to regain more insight in the cardiovascular risk profile of RA patients. Also we want to find out which patients should have more attention concerning their cardiovascular risk profile and probably therapy for...

Ethical review Approved WMO

**Status** Pending

Health condition type Other condition

**Study type** Observational non invasive

## **Summary**

#### ID

NL-OMON33873

#### Source

ToetsingOnline

#### **Brief title**

Endothelial dysfunction measured by PWA in early RA, a longitudinal study

## **Condition**

- Other condition
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

## **Synonym**

rheumatoid arthritis

#### **Health condition**

gewrichtsaandoeningen

## Research involving

Human

## **Sponsors and support**

**Primary sponsor:** Universitair Medisch Centrum Groningen

Source(s) of monetary or material Support: Ministerie van OC&W,research

projectgelden afdeling reumatologie/immunologie

## Intervention

Keyword: Advanced glycation end products, Intima media thickness, Pulse wave analysis

#### **Outcome measures**

## **Primary outcome**

- -Small artery elasticity
- -Intima media thickness
- -Advanced glycation end products in de huid

## **Secondary outcome**

- soluble AGE receptor( s-RAGE)
- endothelial activation markers such as VCAM, vWF, trombomoduline

# **Study description**

#### **Background summary**

In patients with reumatoid arthritis an increased cardivascular morbidity and mortality is present.

We hypothesize that in achieving disease remission also the cardiovascular risk will decrease. We will inverstigate this using the following parameters:

- -Intima media thickness
- -Small artery elasticity
- -Advanced glycation end products in the skin.

## **Study objective**

In this investigation we want to regain more insight in the cardiovascular risk

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profile of RA patients. Also we want to find out which patients should have more attention concerning their cardiovascular risk profile and probably therapy for traditional risk-factors such as hypercholesteolemia and hypertension.

## Study design

We willen 60 patienten includeren met recent gediagnosticeerde RA, die nog niet behandeld zijn en bij hen de uitgangswaarden bepalen wat betreft de surrogaatmarkers voor cardiovasculaire ziekte. Na een jaar en na twee jaar herhalen we de metingen.

60 patiewnts will have to be included with recent onset reumatoid arthritis. In these patients the surrogate markers for atherosclerosis (intima media thickness, small artery elasticity and AGE accumulation in the skin) will be assessed before start of the treatment and after one and two years.

## Study burden and risks

Measurement of IMT/PWA and AGE's every year during 1,5hrs. A total amount of three measurements in two years gives a total of 4,5hrs

## **Contacts**

#### **Public**

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## **Trial sites**

## **Listed location countries**

**Netherlands** 

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# **Eligibility criteria**

#### Age

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

## Inclusion criteria

fulfill the ACR criteria for RA symptoms< 1 year age >18 years not previously received disease modifying antirheumatic drugs.

## **Exclusion criteria**

pregnancy diabetes renal impairment( eGFR>60ml/min) recent surgery myocardial infarction or sepsis in the last three months

# Study design

## **Design**

Study type: Observational non invasive

Intervention model: Other

Allocation: Non-randomized controlled trial

Masking: Open (masking not used)

Control: Active

Primary purpose: Diagnostic

## Recruitment

NL

Recruitment status: Pending

Start date (anticipated): 01-02-2009

Enrollment: 60

Type: Anticipated

## Medical products/devices used

Registration: No

## **Ethics review**

Approved WMO

Application type: First submission

Review commission: METC Universitair Medisch Centrum Groningen (Groningen)

# **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 NL26277.042.08