

# The patient perspective on remission in rheumatoid arthritis

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|                              |                        |
|------------------------------|------------------------|
| <b>Ethical review</b>        | Approved WMO           |
| <b>Status</b>                | Recruiting             |
| <b>Health condition type</b> | Autoimmune disorders   |
| <b>Study type</b>            | Observational invasive |

## Summary

### ID

NL-OMON37359

### Source

ToetsingOnline

### Brief title

The patient perspective on remission in rheumatoid arthritis

### Condition

- Autoimmune disorders

### Synonym

arthritis, RA

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Vrije Universiteit Medisch Centrum

**Source(s) of monetary or material Support:** the European League Against Rheumatism (EULAR)

### Intervention

**Keyword:** patient reported outcome, remission, rheumatoid arthritis

## Outcome measures

### Primary outcome

Domains of patient perceived remission

### Secondary outcome

-

## Study description

### Background summary

Rheumatoid arthritis (RA) is an autoimmune disease characterized by persistent inflammation and subsequent destruction of bone and cartilage in affected joints. Chronic inflammation causes pain and physical impairment, but also fatigue and anxiousness.

Fortunately, due to the development of new drugs, a state of remission is becoming a realistic goal of treatment.

We have been closely involved in formulating the new definition for remission in RA as (executive) members of the committee installed by the EULAR, ACR and OMERACT initiative. During the development process of the new definition, it became apparent that data on patient reported outcomes outside those agreed in the RA core set is scarce. Also knowledge on what patients perceive as remission is absent. These are important problems, since treatment should be targeted at patient relevant outcomes, with patients being crucial partners in obtaining relevant information.

### Study objective

The objective of this study is to understand the patient perspective on remission in RA.

### Study design

Building on our expertise, qualitative METHODS will explore the patient perspective on remission, through focus group discussions with patients in ACR/EULAR remission, self declared remission or in moderate/high disease activity in The Netherlands, Austria and The United Kingdom. From these discussions, domains of remission will be identified.

### Study burden and risks

Patients are asked to come to their own hospital twice within one week time: The first visit involves a regular laboratory visit and joint evaluation, similar to what patients are used to when they visit their rheumatologist. Based on the value of the laboratory tests and the joint evaluation, patients are assigned to one out of three group discussions. During the second visit, the group discussion will take place. In this group discussion, in which 6 to 8 patients will participate, we would like to find out what the patient experience is with very low disease activity.

There are no anticipated risks or discomforts associated with participating in this study, except the visit to the laboratory, which could involve pain at the spot where the needle enters the skin.

## 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

patients with:

- confirmed diagnosis of RA (1987 criteria)
- above 18 years of age

for group 1: fulfilling the ACR/EULAR remission criteria

for group 2: being in self-perceived remission

for group 3: DAS28=>3.2, with 60% having ever had an experience of remission in the past

## Exclusion criteria

- patients who do not sufficiently speak the local language
- patient who do not want to sign the informed consent

## Study design

### Design

|                     |                                 |
|---------------------|---------------------------------|
| Study type:         | Observational invasive          |
| Intervention model: | Other                           |
| Allocation:         | Non-randomized controlled trial |
| Masking:            | Open (masking not used)         |
| Control:            | Active                          |
| Primary purpose:    | Diagnostic                      |

### Recruitment

|                           |            |
|---------------------------|------------|
| NL                        |            |
| Recruitment status:       | Recruiting |
| Start date (anticipated): | 28-06-2012 |
| Enrollment:               | 24         |
| Type:                     | Actual     |

## Ethics review

Approved WMO

|                    |   |
|--------------------|---|
| Date:              | 14-05-2012                                      |
| Application type:  | First submission                                |
| Review commission: | METC Slotervaartziekenhuis en Reade (Amsterdam) |

## 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     | NL40279.048.12 |