The patient perspective on remission in rheumatoid arthritis

Published: 14-05-2012
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The objective of this study is to understand the patient perspective on remission in RA.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Autoimmune disorders
Study type	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

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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