Validation of the EULAR patient-derived rheumatoid arthritis impact of disease (RAID) preliminary score based on patients' perception of the impact of the disease on dimensions of health.

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The objectives of this study are to finalize and validate the preliminary RAID.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Autoimmune disorders
Study type	Observational invasive

Summary

ID

NL-OMON32186

Source
ToetsingOnline

Brief title
RAID

Condition

- Autoimmune disorders
- Joint disorders

Synonym
Rheumatoid arthritis

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: impact on patients, questionnaire, rheumatoid arthritis

Outcome measures

Primary outcome

Validation of the RAID will include several steps:

- Assessment of face, construct and external validity.

- Final choice of tools and of domains

- Reliability

- Sensitivity to change

- Determination of cutoffs defining state and change.

Secondary outcome

not applicable

Study description

Background summary

If it is considered that the aim of treatment in RA is BOTH to prevent later disability AND to treat patients* symptoms, it seems important to use 2 different tools, one related to prediction of disability (i.e. synovitis assessment), and a different score to assess patient perceived symptoms. Some patient questionnaires are available, such as the Health Assessment Questionnaire, HAQ, but they only take into account part of the domains which are important for the patient (e.g. functional assessment for the HAQ). One scale has been developed to incorporate three different dimensions, physical, pain and patient global (the patient activity scale, but patients were not directly involved in the development of this scale.
Thus, to date, to our knowledge, a validated composite index reflecting

patient-perceived impact of RA and taking into account all the domains of importance for the patient does not exist.

Study objective

The objectives of this study are to finalize and validate the preliminary RAID.

Study design

Cross-sectional assessment; international study at 1 time point. The aim is to obtain data from 600 patients, i.e. 50 per country, by establishing a collaborative study in 1 to 3 sites of the participating countries of consecutive patients with RA. For each patient, data will be collected once.
Substudy "reliability"
Longitudinal assessment international study at 2 time points within a 2-7 days interval.
The aim is to obtain data from 60 patients, i.e. 5 per country, a sub-group of the face validity study (above).
Substudy "sensitivity to change"
Longitudinal assessment international study at 2 time points. For each patient, data will be collected twice (10 to 14 weeks interval between assessments). The aim is to obtain data from at least 120 patients, i.e. at least 10 per country; a sub-group of the face validity study (above) or another subset of patients.

Study burden and risks

Burden
During this assessment the patient will fill in the questionnaire and current results of laboratory tests (ESR and CRP) will be collected. Results must be recent (less than 1 week), otherwise an extra blood test.
Patients in the substudy "reliability" (n=5) will return a second time, after 1 week, to fill in the questionnaire and a blood test.
Patients in the substudy "sensitivity to change" (n=10) will return a second time, after 10-14 weeks, to fill in the questionnaire and a blood test.
Risk
No risk

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

Rheumatoid arthritis according to ACR criteria
18 years or older

Exclusion criteria

Early arthritis not definitely RA
Concomitant other inflammatory disease
Severe comorbidity
Patients unable or unwilling to fill in a questionnaire

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	28-10-2008
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO

Date:	24-09-2008
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL22298.029.08