Rheumatoid Arthritis Patients rePort Onset Reactivation

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Joint disorders
Study type	Observational non invasive

Summary

ID

NL-OMON30946

Source
ToetsingOnline

Brief title
RApport

Condition

- Joint disorders

Synonym
arthritis, rheumatoid arthritis

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Wyeth

Intervention

Keyword: cohort, rheumatoid arthritis, self-reported questionnaires, validation

Outcome measures

Primary outcome

RADAI

HAQ

VAS global

Secondary outcome

VAS-fatigue

Coping

Self-efficacy

Ilness perception

Study description

Background summary

Rheumatoid arthritis(RA) is an auto-immune disease affecting the joints of the body. Arthritis and bone erosions are characteristic, causing pain and functional limitations of the involved joints. In the early days RA was mostly untreatable, but over the last 20 years drug treatment has come available which makes arthritis treatable and bone erosions preventable.
By reducing the arthritis activity, it is likely bone erosions could be prevented. This could be done by an adequate prescription of medication, depending on the level of disease activity. This is normally done by the consultant during the visits at the clinic. As flares in RA are very unpredictable, flares could occur just after a visit at the clinic. This will be unobserved by the consultant, but could need a change in medication. In this study we would like to evaluate whether patient could determine their own disease-activity by filling out questionnaires measuring functional status and disease-activity.
If this would be succesful, it could mean that patient will be more able to management the point when there is an urge to see a consultant and change in

medication may be required.

Study objective

This study aims (i)to estimate the monthly change of functional status (HAQ) and self-reported disease activity(RADAI and VAS global) among patient diagnosed with RA, (ii) to estimate the relationship between the changes on DAS28 and changes on the HAQ, RADAI and VAS global and (iii) to determine a cut point on change scores on HAQ, RADAI and VAS global which indicates a flare of disease activity (DAS28>3.2) requiring treatment.

Study design

Longitudinal predictive cohort study, predicting disease flares (DAS28>3.2) by HAQ, RADAI and VAS global.

150 RA patients will be invited to participate in this study. A letter will be send to them including a patient information leaflet about the study. Patients could be included if they are using at least 3 months 'disease modyfing drugs', age over 17 years and sufficient knowledge to read and write Dutch. Patient with severe psychiatric illness or personalty disorders, no access to a computer at home or no access to internet or email will be excluded.
Patients will be asked to complete a questionnaire monthly via internet and to visit the nurse-practioner 3-monthly over a period of 1 year. The nurse-practioner will determine the disease-activity score(DAS) using physical examination.
Data will be analysed using STATA 8.0. Linear regression will be used to evaluate the relationship between changes in DAS28 scores and change in scores on the self-reported measures. Multivariate linear regression will be used to predict the change in DAS28-score by the change scores of the HAQ, RADAI and VAS global. Receiver operating characteristic (ROC) curves will be plotted to explore sensitivity and specificity of a flare (DAS>3.2) for all possible cut off points of the change in HAQ, RADAI and VAS. Discriminate ability will be calculated using the area under the curve.

Study burden and risks

It will take about 30 minutes to fill out the baseline questionnaire
It will take 30 minutes a visit to the nurse practioner
Completing the follow-up questionnaires will take about 10-15 minutes

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 ACR-classified RA using DMARDs for at least 3 months.

Exclusion criteria

younger than 18 years
Not able to read and write in Dutch
Severe psychiatric illness or personality disorders
Not able to use a computer
No availability of internet and/or email

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	07-01-2008
Enrollment:	150
Type:	Actual

Ethics review

Approved WMO

Date:	13-12-2007
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (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	NL19149.078.07