The Patient based Disease Activity Score (PDASII) validation study

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The aim of this study is to assess the effect of training on the measurement properties of a recently developed disease activity score based on patient reported outcomes and to investigate if such a measure could be implemented in current clinical...

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

Summary

ID

NL-OMON35066

Source
ToetsingOnline

Brief title
The PDASII study

Condition

- Autoimmune disorders
- Muscle disorders

Synonym
chronic joint inflammation, Rheumatoid Arthritis

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Het Reumafonds

Intervention

Keyword: Disease Activity, Patient reported outcomes, PDASII, Rheumatoid Arthritis

Outcome measures

Primary outcome

The primary focus of this study is the effect of training on the concurrent criterion validity of the PDASII. Primary outcome of the study will be the mean difference between the PDASII and DAS28 at 6, 9 and 12 months after baseline.

Secondary outcome

Secondary outcomes will be other clinimetric aspects of the PDASII:

Validity

- face/content; percentage found to be comprehensive and percentage missing elements
- construct; convergent correlation analysis with other measures of disease activity and
related components of health assessment questionnaires, discriminant correlation
analysis with non-related components of health assessment questionnaires
measures of disease activity and health state measures
- criterion; with joint damage progression over the course of one year

Reliability

- intraobserver intra-class correlation coefficient

Sensitivity to change

- standardised response mean

- effect size

- minimal important difference (ROC + 75th percentile)

Feasibility

- average time to complete

- average cost to complete

- percentage positive interpretability

- percentage full-completion

Acceptance

- percentage physicians and patients willing to use patient reported measure

for monitoring

Study description

Background summary

In recent years there has been a trend in medical practice towards patient-centred care. Within rheumatology attention is being paid to finding outcome measures with which patients can track their disease process; hereby exploring effective and efficient ways to evaluate therapy.

Study objective

The aim of this study is to assess the effect of training on the measurement properties of a recently developed disease activity score based on patient reported outcomes and to investigate if such a measure could be implemented in current clinical practice.

Study design

This study has a randomised parallel group design. Patients seen in daily clinical practice are studied with three-monthly follow-up assessments for the duration of one year. After being invited to take part in the study, patients will be randomised to receive elaborate training or standard written instructions on how to perform joint counts. The group of patients receiving elaborate training will receive verbal and written instructions, and a video how to assess and report joint counts. During the first two visits (out of five) discrepancies between the PRO*s and standard clinical assessments will be discussed in order to minimize these. The group of patients randomised not to receive training will be given standard written instructions on how to perform joints counts.

Intervention

During the course of one year, various patient reported measures, such as the Patient-based Disease Activity Score (P-DASII), the modified Rheumatoid Arthritis Disease Activity Index (RADAI-5), the Routine Assessment of Patient Index Data (RAPID 2-5), the Patient derived Disease Activity Score 28 joint count (Pt-DAS28) the Health Assessment Questionnaire Disability Index (HAQ-DI), the Short Form 36 questions (SF36) and the Euroqol 5D (EQ-5D) will be collected at baseline and three-monthly follow-up visits. A trained research nurse will assess patients during these visits providing a Disease Activity Score 28 joint count (DAS28) and a Clinical Disease Activity Index (CDAI), which are currently used in clinical practice. Furthermore radiographs of the hands and feet will be taken at baseline and twelve months follow-up to assess joint damage progression.

Study burden and risks

Due to the nature of this study, there is no extra risk involved with participation in de study. Patient burden will be approximately 45 minutes for each visit.

Contacts

Public
UMC St Radboud

Geert Grooteplein 8
6500HB Nijmegen
NL
Scientific

UMC St Radboud

Geert Grooteplein 8
6500HB Nijmegen
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. Diagnosis RA according to the ACR criteria
2. Patients starting on either their first DMARD or biological therapy

Exclusion criteria

Patients who are unable to complete the questionnaires/PDASII

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Other

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	05-10-2011
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO Date:	07-10-2010
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	12-07-2012
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL31935.091.10