Validity and feasability of self-assessment of joints by patients with rheumatoid arthritis and the influence of elaborate training.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20270

Source
NTR

Brief title
PDASII validation study

Health condition

Rheumatoid Arthritis, reumatoïde artritis, patient reported outcomes, patiënt gerapporteerde uitkomsten, self assessed joint counts, zelfonderzoek, training,PDASII, validation, validatie, clinimetrics, klinimetrie

Sponsors and support

Primary sponsor: Radboud University Nijmegen medical Centre.
Source(s) of monetary or material Support: Reumafonds (Dutch arthritis association).

Intervention

Outcome measures

Primary outcome

Concurrent longitudinal validity of the PDASII with the DAS28 at 6, 9 and 12 months follow-up by means of a random effect model with training yes/no as a independent variable.

Secondary outcome

Validity:

1. Face/content: Percentage found to be comprehensive versus missing elements;

2. 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;

3. Predictive analysis of PDASII with joint damage progression.

Reliability:

1. PDASII intrarater intra-class correlation coefficient.

Sensitivity to change:

1. Standardised response mean;

2. Effect size;

3. Minimal important difference (ROC + 75th percentile).

Training:

The above mentioned analyses can be performed with ‘training’ as an covariate to assess the effect of having received training on the measurement properties of the PDASII.

Study description

Background summary

Background:

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 with Rheumatoid Arthritis (RA) can track their disease process; hereby exploring effective and efficient ways to evaluate therapy.

Objective:

The objective of this study is:

1. To assess the measurement properties of a RA disease activity score based on patients' self assed joint scores, and;

2. To assess the effect of training on these measurement properties.

Methods:

For this study we will include a broad range of RA patients, who are seen in daily clinical practice. Patients seen three months after being diagnosed and patients switching to immune modulating therapy will be invited to take part in this study. Patients will be randomised to receive joint count training or not, and will be followed for one year. In this follow up period the various measures will be collected such as: the Disease Activity Score 28 joint count (DAS28), the Clinical Disease Activity Index (CDAI), the patient-based Disease Activity Score version two (P-DASII), as well as other patient reported outcomes, such as the Health Assessment Questionnaire Disability Index (HAQ-DI), the Routine Assessment of Patient Index Data (RAPID 2-5), the modified Rheumatoid Arthritis Disease Activity Index (RADAI-5), the Patient derived Disease Activity Score 28 joint count (Pt-DAS28), the Short Form 36 Health Survey (SF-36) and Euroqol 5D (EQ-5D). In addition to these measures, radiographs of the hands and feet will be taken at baseline and 12 months follow-up to assess joint damage progression.

Validity will be investigated by comparing the course of the PDASII and the other measures over time. Reliability of the self assessed joint counts will be investigated by obtaining these measures twice, with a two day separation period (test-retest). Sensitivity of the PDASII will be assessed and compared to the sensitivity of the DAS28 and CDAI. The effect of training will be analysed by performing the analyses with training as a covariate.

Results:

Data from this study will elucidate the value of patient reported outcomes for the monitoring of treatment. Based on this information a monitoring strategy can be developed, where effectiveness, cost effectiveness, patient participation and time efficiency will be optimised.

Ultimately this will lead to patient care, where patients' interests and participation are central and where clinical measurement instruments and physicians' expertise are optimally utilized to achieve the best possible results.

Study objective

Elaborate training will have a positive longterm effect on the longitudinal measurement properties of the PDASII.

Study design

Patients are followed for one year at regular three monthly visits.

Intervention

Standard joint assessment instructions vs elaborate joint assessment training by means of extended written instructions including photographs, an instructional video on the performance of self-assessment of the joints and two verbal feedback sessions with a trained research nurse at baseline and three months follow-up.

Contacts

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Eligibility criteria

Inclusion criteria

1. Early RA patients seen 3 months post diagnosis or;

2. Patients starting on immunomodulating therapy (biological).

Exclusion criteria

1.Patients younger than 18 years of age;

2.Patients totally incapable of performing the PDASII evaluation;

3.Patients unwilling to be randomised between training groups.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2011
Enrollment:	200
Type:	Anticipated

Ethics review

Positive opinion

Date:	25-11-2010
Application type:	First submission

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
NTR-new	NL2510
NTR-old	NTR2628
Other	CMO regio Arnhem Nijmegen : 2010/300
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

N/A