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

Gepubliceerd: 25-11-2010 Laatst bijgewerkt: 13-12-2022

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

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20270

Bron
Nationaal Trial Register

Verkorte titel
PDASII validation study

Aandoening

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

Ondersteuning

Primaire sponsor: Radboud University Nijmegen medical Centre.
Overige ondersteuning: Reumafonds (Dutch arthritis association).

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

2. Patients starting on immunomodulating therapy (biological).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-01-2011
Aantal proefpersonen:	200
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	25-11-2010
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2510

Register	ID
NTR-old	NTR2628
Ander register	CMO regio Arnhem Nijmegen : 2010/300
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A