Evaluating patient reported outcomes in the treatment practice of patients with rheumatoid arthritis

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Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON25449

Bron
Nationaal Trial Register

Aandoening

Patient Reported Outcomes, PROs
Rheumatoid Arthritis, RA
Intensive outpatient management
Tight Control
Treat to target (T2T)

Ondersteuning

Primaire sponsor: none
Overige ondersteuning: none

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Patient reported outcomes (RAPID-3) and DAS28

Toelichting onderzoek

Achtergrond van het onderzoek

This is a prospective observational study, addressing the relationship between DAS28 scores and RAPID3 questionnaires during the treatment of rheumatoid arthritis in adults. Four rheumatologists each assessed patients with rheumatoid arthritis in “real time” clinical care. The rheumatologist or nurse practioner performed a 28-joint count. Patients,recruited in the Netherlands, are emailed and asked to complete the RAPID3 questionnaire. The questionnaire takes 5-10 minutes to complete. The performed RAPID3 will be compared with the DAS28 on a 0-30 versus 1-10 scale. Scores are classified as high activity, moderate activity, low activity, and remission according to the DAS28 and RAPID3 scores. The DAS28 and RAPID3 scores will be statistically compared with a spearman’s rank correlation and with Cohen's kappa coefficient. The questionnaire is processed by an online data portal, which is protected and certified with ISO 9001/ ISO 27001.

Doel van het onderzoek

The validated health assessment questionnaire (HAQ) such as the RAPID3, gives the rheumatologist the opportunity to have a more frequent and objective view on the effectivity and safety of the treatment. There is a relation between the RAPID3 and the DAS28 in clinical practice.

Onderzoeksopzet

% with Routine Assessment of Patient Index Data with 3 measures (RAPID3) Timepoints: 4 times a year. % with Disease Activity Score in 28 joints (DAS28) Timepoints: 4 times a year.

Onderzoeksproduct en/of interventie

N/A

Contactpersonen

Publiek

[default]

The Netherlands

Wetenschappelijk

[default]
The Netherlands

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Adults with reumatoïde artritis treated with biologicals, such as TNFα-blockers (etanercept, adalimumab, infliximab etc.), interleukine-I-blockers, the B-celblocker rituximab, and the T-celactivationblocker and anti CTLA4 (abatacept).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

non RA patients, no biological treatment, non adult,

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	10-09-2013
Aantal proefpersonen:	300

Type: Verwachte startdatum

Ethische beoordeling

Positief advies
Datum: 30-08-2013
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	NL3983
NTR-old	NTR4155
Ander register	METC ATRIUM ORBIS ZUYD : 13-N-100
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A