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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON25449

Source
Nationaal Trial Register

Health condition

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

Sponsors and support

Primary sponsor: none
Source(s) of monetary or material Support: none

Intervention

Outcome measures

Primary outcome

Patient reported outcomes (RAPID-3) and DAS28

Secondary outcome

Side effects

Study description

Background summary

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.

Study objective

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.

Study design

% 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.

Intervention

N/A

Contacts

Public

[default]

The Netherlands
Scientific

[default]
The Netherlands

Eligibility criteria

Inclusion criteria

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).

Exclusion criteria

non RA patients, no biological treatment, non adult,

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	10-09-2013
Enrollment:	300
Type:	Anticipated

Ethics review

Positive opinion

Date:	30-08-2013
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	NL3983
NTR-old	NTR4155
Other	METC ATRIUM ORBIS ZUYD : 13-N-100
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A