Biologicals and tsDMARDs in inflammatory rheumatic diseases: The Reade Rheumatology Registry

No registrations found.

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

Summary

ID

NL-OMON28595

Source
Nationaal Trial Register

Health condition

inflammatory rheumatic diseases, biologic agents, targeted synthetic DMARD, safety, efficacy, dose reduction strategy

Sponsors and support

Primary sponsor: Reade Rheumatology, Amsterdam
Source(s) of monetary or material Support: fund = initiator = sponsor

Intervention

Outcome measures

Primary outcome

Efficacy will be determined in comparison to baseline by comparing disease activity, patient reported outcomes, radiological progression and functional capacity during follow-up.

Safety will be determined by the occurrence of side effects.

Secondary outcome

Changes in (bio)markers during treatment will be analyzed versus baseline.

Study description

Background summary

Rationale: 1) Biologicals and targeted synthetic Disease Modifying AntiRheumatic Drugs (tsDMARD) are approved in the Netherlands for the treatment of moderate to severe rheumatoid arthritis (RA), psoriatic arthritis (PsA) or ankylosing spondylitis (AS)/non-radiographic axial spondyloarthritis (nrAxSpA). As efficacy in daily clinical practice can differ from the clinical (registration) trials, e.g. due to different patient groups, it is important to monitor the daily clinical practice. 2) Nowadays treatment of RA, PsA and AS (nrAxSpA) is to a large extent protocolized and aimed at achieving remission. After achieving remission it is important to taper or even stop the antirheumatic drugs to avoid unnecessary drug exposure. Identifying (bio)markers for treatment response, failure and successful tapering will improve treatment response.

Objective: To determine the efficacy and safety of biological agents and tsDMARDs in rheumatoid arthritis, ankylosing spondylitis and psoriatic arthritis patients in daily clinical practice. In addition, prognostic (bio)markers for treatment response, failure and successful tapering will be identified.

Study design: Prospective observational cohort study in patients with RA, PsA, AS (nrAxSpA) who are treated with biologics or tsDMARDs or in whom treatment with these agents is initiated. Efficacy and safety data will be collected throughout the study.

Main study parameters: Efficacy will be determined in comparison to baseline by comparing disease activity, patient reported outcomes, radiological progression and functional capacity during follow-up.

Safety will be determined by the occurrence of side effects. Changes in (bio)markers during treatment will be analyzed versus baseline.

Study design

Baseline (prior to treatment) and 1 month, 3-4 months, 6-7 months, 1 year, 1,5 year, 2 years

and yearly thereafter.

Intervention

none

Contacts

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Eligibility criteria

Inclusion criteria

- Rheumatoid arthritis, psoriatic arthritis or ankylosing spondylitis/non-radiographic axial spondyloarthritis, according to the treating rheumatologist;

- Written informed consent.

Exclusion criteria

None

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	24-11-2016
Enrollment:	0
Type:	Anticipated

Ethics review

Positive opinion

Date:	21-11-2017
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	NL6698
NTR-old	NTR6868
Other	METC Slotervaartziekenhuis en Reade : P1660

Study results