Prospective follow-up study of subcutaneous tocilizumab (RoActemra®) treatment in rheumatoid arthritis.

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To determinate the efficacy and safety of subcutaneous (s.c.) tocilizumab in patients with rheumatoid arthritis in a daily clinical setting. In addition, to monitor the effect of treatment with tocilizumab s.c. on the lipid profile, markers of bone...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Joint disorders
Study type	Observational non invasive

Summary

ID

NL-OMON41073

Source
ToetsingOnline

Brief title
Subcutaneous tocilizumab in rheumatoid arthritis

Condition

- Joint disorders

Synonym
rheumatic disease, rheumatoid arthritis

Research involving
Human

Sponsors and support

Primary sponsor: Jan van Breemen Instituut
Source(s) of monetary or material Support: Reade/Jan van Breemen Instituut

Intervention

Keyword: Rheumatoid arthritis, Subcutaneous tocilizumab

Outcome measures

Primary outcome

- DAS28 score and response is defined as the EULAR criteria of a good or

moderate response and a score of <3.2

- Effect on RAPID-3/MDHAQ-2

Secondary outcome

- The number of adverse events (infections, malignancies, mortality)

- ESR and/or CRP

- The lipid profile

- Inflammation processes

- Relation between genetic polymorphisms and the efficacy of tocilizumab

- Radiographic progression

- Changes in bone mineral density

- Cardiovascular risk factors

Study description

Background summary

Recently, tocilizumab s.c. is available in the Netherlands for the treatment of rheumatoid arthritis. It is important to determine efficacy and safety in daily clinical practice, because this can differ from clinical trials. Further, prognostic markers can be determined.

Study objective

To determinate the efficacy and safety of subcutaneous (s.c.) tocilizumab in

patients with rheumatoid arthritis in a daily clinical setting. In addition, to monitor the effect of treatment with tocilizumab s.c. on the lipid profile, markers of bone metabolism, and risk factors for cardiovascular disease.

Study design

Prospective observational cohort study in rheumatoid arthritis patients starting with tocilizumab s.c. The first visit will take place before the start of treatment and the patient will be followed at 1 month, 4 months, 6 months, 1 year, 1.5 year, 2 years, and once yearly thereafter.

Study burden and risks

The additional burden consists of an extra blood sample taken at moments that this would already have been done in view of routine patient care. At each visit 12.5 ml blood will be collected and stored (encoded) at Reade with the purpose to answer future research questions concerning treatment with subcutaneous tocilizumab. During the first visit only, an extra 22 ml of blood will be collected for research into genetic factors whom are of potential influence on the process of inflammation and are potential predictors for response to therapy.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients:
- who are diagnosed with RA;
- in whom tocilizumab s.c. is prescribed by their treating rheumatologist; and
- who gave written informed consent.
Both bio-naive patients as patients who failed on previous biologic agents will be included.

Exclusion criteria

Patients with contraindications for tocilizumab treatment. For patients previously treated with intravenous tocilizumab a washout period of 4 weeks is required.

Study design

Design

Study phase:	4
Study type:	Observational non invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	22-06-2015
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO Date:	15-12-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC

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
CCMO	NL50732.048.14