Long term prospective follow-up study of tocilizumab (RoActermraR) administered to patients with rheumatoid arthritis in daily clinical practice.

Published: 28-04-2010
Last updated: 16-11-2024

To determine the efficacy and safety of tocilizumab in the daily clinical practice situation for at least 36 months in comparison to the reported efficacy and safety in clinical trials.There will be a particular focus of the effect of tocilizumab on...

Ethical review	Approved WMO
Status	Completed
Health condition type	Autoimmune disorders
Study type	Observational non invasive

Summary

ID

NL-OMON34333

Source
ToetsingOnline

Brief title
tocilizumab in rheumatoid arthritis

Condition

- Autoimmune disorders
- Joint disorders

Synonym
inflammatory disease

Research involving
Human

Sponsors and support

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

Intervention

Keyword: rheumatoid arthritis, tocilizumab

Outcome measures

Primary outcome

Efficacy will be determined in comparison to baseline by comparing disease

activity, radiological progression and functional capacity during follow-up.

Safety will be determined by the occurrence of (serious) side effects.

Secondary outcome

There will be a particular focus of the effect of tocilizumab on lipid profile,

bone density changes as well as risk factors for cardiovascular disease and

osteoporosis.

prognostic determinators will be assessed.

Study description

Background summary

Tocilizumab, an IL-6 inhibitor, has recently been approved in the Netherlands for the treatment of moderate to severe rheumatoid arthritis (RA). As clinical efficacy (and safety) 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. In addition, prognostic determinators can be assessed.

Study objective

To determine the efficacy and safety of tocilizumab in the daily clinical practice situation for at least 36 months in comparison to the reported

efficacy and safety in clinical trials.
There will be a particular focus of the effect of tocilizumab on lipid profile, markers of bone metabolism as well as risk factors for cardiovascular disease and osteoporosis.

Study design

Prospective observational follow-up study

Study burden and risks

Patients will be treated intravenously at the day care unit of the outpatient clinic at the Jan van Breemen Institute. The additional *burden* consists of an extra amount of blood (approximately 20 cc) at moments that this would already have been done in view of routine patient care. The patients will also be asked to give urine at the same moments as mentioned above. This will be done 7 times in the first year en every half year after the first year.

Contacts

Public
Jan van Breemen Instituut

Dokter Jan van Breemenstraat 2
1056 AB Amsterdam
NL
Scientific
Jan van Breemen Instituut

Dokter Jan van Breemenstraat 2
1056 AB Amsterdam
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

rheumatoid arthritis and treatment with tocilizumab

Exclusion criteria

contraindications for treatment with tocilizumab
No signed informed consent

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:	Completed
Start date (anticipated):	25-08-2010
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO

Date:	28-04-2010
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	30-11-2011
Application type:	Amendment
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	NL32159.048.10