Long term prospective observational cohort study on the safety and efficacy of abatacept subcutaneus in the daily clinical practice of rheumatoid arthritis

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To determine the efficacy and safety of abatacept SC in rheumatoid arthritis patients in daily clinical practice over 24 months. In addition, the retention rate of abatacept SC will be assessed during this study.

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

Summary

ID

NL-OMON39013

Source
ToetsingOnline

Brief title
Abatacept subcutaneous in rheumatoid arthritis

Condition

- Joint disorders

Synonym
Inflammatory rheumatic disease

Research involving
Human

Sponsors and support

Primary sponsor: Jan van Breemen Instituut

Source(s) of monetary or material Support: Reade centrum voor revalidatie en reumatologie

Intervention

Keyword: Abatacept subcutaneous, Efficacy, Rheumatoid arthritis, Safety

Outcome measures

Primary outcome

Efficacy will be determined in comparison to baseline by measuring disease

activity, radiological progression and

functional capacity during follow-up. Safety will be determined by the

occurrence of side effects.

Secondary outcome

nvt

Study description

Background summary

1) Abatacept, a co-stimulation blocker via CD 86 competition, has recently been approved as subcutaneous (SC) injections in the Netherlands for the treatment of moderate to severe rheumatoid arthritis. 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) Recent evidence suggests that Abatacept SC has a low immunogenicity and favorable safety and clinical efficacy in patients with RA when administered in the presence or absence of background MTX and in the absence of an initial intraveneous (IV) loading, this should be further investigated in daily clinical practice

Study objective

To determine the efficacy and safety of abatacept SC in rheumatoid arthritis patients in daily clinical practice over 24 months. In addition, the retention

rate of abatacept SC will be assessed during this study.

Study design

Prospective observational cohort study of patients diagnosed with moderate to severe active RA and initiated and treated with abatacept SC. Efficacy and safety data will be collected throughout the study.

Study burden and risks

Consists of an extra blood sample taken concurrently with regular/routine laboratory testing.Optionally genetic factors directly influencing the inflammatory process will be determined. Reference samples might be used for example for determination of glucose metabolism, lipd profile and inflammatory markers.

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 * 18 years old at treatment initiation
Patients informed and accepting to participate (Written informed consent)
Patients diagnosed with established moderate to severe active RA as per the 1987 ACR criteria/2010 ACR/EULAR Rheumatoid Arthritis Classification Criteria
Patients who at their physician*s discretion are initiated with abatacept SC.

Exclusion criteria

Patients currently participating in any interventional clinical trial in RA
Contraindications against abatacept SC treatment.

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):	18-09-2013
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO

Date:	13-08-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	20-02-2014
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	NL45634.048.13