Prospective follow-up study of ustekinumab treatment in psoriatic arthritis

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To determine the efficacy and safety of ustekinumab in patients with PsA in a daily clinical setting. In addition, the effect of treatment with ustekinumab on the lipid profile, markers of bone metabolism, and risk factors for cardiovascular disease...

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

Summary

ID

NL-OMON40967

Source
ToetsingOnline

Brief title
Ustekinumab in psoriatic arthritis

Condition

- Joint disorders

Synonym
psoriatic arthritis, rheumatic disease

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: Psoriatic arthritis, Ustekinumab

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

- PASI response

- Effect on HAQ-DI

Secondary outcome

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

- LEI improvement

- Number of nails with nail psoriasis

- ESR and/or CRP

- The lipid profile

- Inflammation processes

- Relation between genetic polymorphisms and the efficacy of ustekinumab

- Radiographic progression

- Changes in bone mineral density

- Cardiovascular risk factors

Study description

Background summary

Recently, ustekinumab is available in the Netherlands for the treatment of psoriatic 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 determine the efficacy and safety of ustekinumab in patients with PsA in a daily clinical setting. In addition, the effect of treatment with ustekinumab on the lipid profile, markers of bone metabolism, and risk factors for cardiovascular disease will be monitored during this study.

Study design

Prospective observational study of all patients with PsA treated with ustekinumab. The first visit will take place before the start of the 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

During every visit questionnaires are taken and physical examination is performed, which is part of routine patient care. Also blood samples are collected. Next to the routine blood samples an extra extra blood sample is taken for the study. There are no additional risks for the patient.

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 psoriatic arthritis;
- in whom ustekinumab is prescribed by their treating rheumatologist; and
- who gave written informed consent.
Both biological naive patients as patients who failed on TNF-blocking agents are included.

Exclusion criteria

Patients with contraindications for ustekinumab 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):	15-01-2016

Enrollment:	50
Type:	Actual

Ethics review

Approved WMO Date:	15-10-2014
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	NL50530.048.14