Musculoskeletal ultrasound to assess therapeutic effects of novel antirheumatic therapies in Psoriatic Arthritis

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

Summary

ID

NL-OMON46720

Source
ToetsingOnline

Brief title
MSUS PsA

Condition

- Joint disorders
- Epidermal and dermal conditions

Synonym
inflammatory arthritis, psoriatic arthritis

Research involving
Human

Sponsors and support

Primary sponsor: Reade
Source(s) of monetary or material Support: Reade

Intervention

Keyword: Apremilast, Psoriatic Arthritis, Secukinumab, Ultrasound

Outcome measures

Primary outcome

The main outcomes of the study are the early ultrasound findings (baseline.

week 2 and week 4) and the clinical therapeutic response to apremilast and

secukinumab at 24 weeks

Secondary outcome

Secondary outcomes of the study are ultrasound findings and clinical

assessments at all time points.

Study description

Background summary

Psoriatic arthritis is an inflammatory joint disease. Patients with psoriatic arthritis can be treated with various medications acting upon the inflammatory responses and the immune system, such medications may have various mechanisms of action. Examples are methotrexate and anti-TNF medication. Recently two new therapies for psoriatic arthritis with a new mechanism of action have been approved: apremilast and secukinumab. For both apremilast and secukinumab clinical trials have shown good results on both the skin and the joints. Ultrasound is a technique used to image joints and tendons. Ultrasound can also be used to image skin and nails, however up until now this has not been done very often.

Study objective

In this study we want to investigate whether early ultrasound findings (e.g. baseline, 2 and 4 weeks) in both joints, tendons, nails and skin can predict

response to therapy with apremilast and secukinumab. Also, we want to investigate whether ultrasound findings in joints, tendons, nails and skin can provide additional information in monitoring treatment with apremilast and secukinumab in patients with psoriatic arthritis, next to clinical assessments.

Study design

Multi-center longitudinal prospective observational cohort study

Study burden and risks

Participation in scientific research takes extra time for the patients. During the study visits, blood will be drawn, which can be associated with pain at the needle insertion or a small hematoma after the blood collection. On the other hand, patients might appreciate it to be looked after more often during the start up of new medication than during normal care. Additionally, the results of the study will hopefully result in better care for psoriatic arthritis patients. The ultrasound investigation is non-invasive and safe.

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

- 18 years or older
- Active psoriatic arthritis, defined as *2 swollen and *2 tender joints
- Starting with apremilast, secukinumab or anti-TNF therapy

Exclusion criteria

- Other active concomitant musculoskeletal disease

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-05-2018
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO

Date:	23-01-2018
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	NL64072.048.17

Study results

Date completed:	21-04-2021
Actual enrolment:	4

Summary results
Trial ended prematurely