Low disease activity in psoriatic arthritis: a cross-sectional analysis of a cohort of patients with Psoriatic Arthritis

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Primary objectives:1) to determine the residual disease activity in a large cohort of patients with PsA in whom the treating physician considers the disease adequate-controlled under the current treatment.2) to document the different treatment...

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

Summary

ID

NL-OMON39993

Source
ToetsingOnline

Brief title
LDA in PsA

Condition

- Autoimmune disorders
- Joint disorders

Synonym
psoriatic arthritis, spondyloarthritis

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: collectebusfondsen

Intervention

Keyword: - cross-sectional, - low disease activity, - psoriatic arthritis

Outcome measures

Primary outcome

- Disease activity will be assessed in all potential disease domains.

- The proportion of patients that fulfills the criteria for Minimal Disease

Activity (MDA) will be determined.

- The proportion of patients that fulfills the criteria for MDA in DMARD

treated versus TNFi treated patients.

- Current medication (type, dosage and start date) will be documented

Secondary outcome

- Parameters related to cardiovascular outcomes will be assessed.

- Depression, quality of life, and work participation.

- Determination of biomarkers and genetic markers

Study description

Background summary

Psoriatic arthritis (PsA) is a chronic inflammatory disease. Treatment with traditional disease modifying anti-rheumatic drugs (DMARDs) or biological agents, including TNF inhibitors may be necessary to reduce the signs and symptoms of disease, and prevent joint damage. Ideally, the treating physician evaluates the symptoms and severity in all disease domains where PsA may be active; skin and nails, arthritis, dactylitis, enthesitis and spondylitis but also inflammatory bowel disease and uveitis. The 'tight control' and 'treat-to-target' principles that are commonly applied in rheumatoid arthritis (RA) have not yet been evaluated and or implemented in PsA. This "tight control" for PsA as well can be induced by using the criteria for "minimal active disease". Our hypothesis is that a significant proportion of PsA patients still have residual disease activity and thus may theoretically

benefit from more intensive treatment (after future studies).

Study objective

Primary objectives:
1) to determine the residual disease activity in a large cohort of patients with PsA in whom the treating physician considers the disease adequate-controlled under the current treatment.
2) to document the different treatment regimens in these patients.

Secondary objectives
1) to determine prevalence of other important co-morbidities, including the cardiovascular disease, depression and alcohol (ab)use
2) to determine which biomarkers are able to predict MDA

Study design

A *two center* cross-sectional descriptive cohort study in patients with PsA in whom the treating physician considers the disease is well-controlled. Patients will be recruited from the outpatient clinic in Reade and AMC regardless of treatment regimen.

Study burden and risks

- 1 visit (1,5 hours) is planned.
- a questionnaire will be performed with a duration of 15 minutes
- 1x blood will be drawn. The total amount is 37ml (8 tubes)

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

psoriatic arthritis en voldoen aan classificatie criteria for psoriatic arthritis (CASPAR)
low disease activity according to rheumatologist no matter what therapy

Exclusion criteria

concomittant rheumatic diseases other than psoriatic arthritis
other painful conditions that may interfere the disease activiity evaluations

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-02-2013

Enrollment:	250
Type:	Actual

Ethics review

Approved WMO Date:	12-12-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	05-03-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-03-2013
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	NL42303.018.12