Extended systems medicine protocol to understand the development of psoriatic arthritis

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Objective: We want to extend our understanding of the disease aetiology by performing a small pilot study that incorporates other immunologic sites involved in the disease (the skin and the microbiome) while additionally strengthening our disease...

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

Summary

ID

NL-OMON43948

Source
ToetsingOnline

Brief title
Extend-UP

Condition

- Autoimmune disorders
- Joint disorders
- Epidermal and dermal conditions

Synonym
Psoriasis; psoriatic arthritis

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht

Source(s) of monetary or material Support: Johnson & Johnson, unrestricted educational grant,Johnson & Johnson;unrestricted educational grant

Intervention

Keyword: ankylosing spondylitis, psoriasis, psoriatic arthritis, systems medicine

Outcome measures

Primary outcome

-Integrative systems medicine profile will be derived from blood samples (RNA sequencing, micro RNA profiling, genome-wide methylation, flow-cytometry; same as in protocol 13-696), skin biopsies (immunohistochemistry and single cell sequencing), and microbiome (skin/gut 16S rRNA sequencing).

-Established disease activity parameters will be assessed (e.g. joint count, enthesitis count, CRP) along with novel disease activity parameters aimed at detecting early (sub-clinical) changes in the joint/enthesis (i.e. MRI of the feet; whole body FDG-PET/CT).

Group differences with respect to systems medicine profile and novel radiographic imaging will be compared between Pso and PsA (with AS serving as disease control group). The relationship between the early changes in the joint/enthesis (as detected with novel imaging) will be compared to the underlying molecular pathways (as detected by integrative systems medicine profile).

Secondary outcome

The prospective value of integrative systems medicine profile and (novel)

disease activity parameters on disease course and response to treatment will be evaluated.

Novel imaging techniques (MRI of the feet; whole body FDG-PET/CT) will be compared to established disease activity parameters to evaluate their complementary/additional use as disease-activity parameters.

Study description

Background summary

Rationale: Patients with psoriatic arthritis have a reduced quality of life and would greatly benefit from the identification of novel diagnostic markers capable of detecting early stages of disease and the identification of novel therapeutic targets. Protocol 13-696 is currently investigating the molecular pathways driving the development of psoriatic arthritis in a large cohort of patients. Protocol 13-696 is using the systems medicine approach to identify novel therapeutic and diagnostic markers derived from blood samples in study participants.

Study objective

Objective: We want to extend our understanding of the disease aetiology by performing a small pilot study that incorporates other immunologic sites involved in the disease (the skin and the microbiome) while additionally strengthening our disease outcome measures (by including novel imaging techniques that can detect early stages of the disease).

The primary objectives are
1) To identify novel diagnostic targets aimed at differentiating psoriasis limited to the skin from psoriatic arthritis
2) To identify novel therapeutic targets aimed at joint and enthesis inflammation in (early) psoriatic arthritis

The secondary objectives are
3) To identify prognostic markers of disease course and response to treatment
4) To identify severity-of-disease markers that reflect the disease

activity/severity

Study design

Study design: Observational, longitudinal study for a maximum duration of two years being conducted in the outpatient clinic of the dermatology and rheumatology departments.

Study burden and risks

Per participant the following study interventions will be performed :
-three times vena puncture (80mL drawn each time): negligible risk
-one time 4 skin biopsies (4mm): low risk
-one time microbiome samples collected (faeces sample and skin swab): negligible risk
-one time FDG-PET(CT) whole body: low risk
-three times MRI-feet with gadolinium contrast: low risk
-three times questionnaires: negligible risk
-in psoriasis patients specifically, three times clinical evaluation including X-rays of hands and feet which are not part of standard care: negligible risk

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

* Cohort Pso: N<=25 patients with psoriasis
* Cohort PsA: N<=25 patients with psoriatic arthritis
* Cohort AS: N<=25 patients with ankylosing spondylitis;age 18-55

Exclusion criteria

Use of immunomodulatory drugs
Contraindications to FDG-PET/CT, MRI scanner

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-03-2016
Enrollment:	75
Type:	Actual

Ethics review

Approved WMO Date:	17-11-2015
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	01-08-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL53860.041.15