Discovery of Arthritis in Psoriasis Patients for Early Rheumatological referral (DAPPER

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To ascertain the prevalence of PsA in a tertiary PsO cohort. Secondary objectives will be to ascertain the clinical features of these patients. With these features we want to find clinical, laboratory or genetic markers to predict the presence of...

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

Summary

ID

NL-OMON48399

Source
ToetsingOnline

Brief title
DAPPER

Condition

- Joint disorders
- Epidermal and dermal conditions

Synonym
psoriasis, psoriatic arthritis

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: prevalence, psoriasis, psoriatic arthritis

Outcome measures

Primary outcome

The prevalence of (newly discovered) PsA in known PsO patients in the setting

of a university dermatology outpatient clinic.

Secondary outcome

Secondary endpoints will be the difference between both populations with regard

to several markers. These markers will be used to develop a new screening tool.

QoL parameters, and the change after 1 year, will also be evaluated.

Study description

Background summary

Psoriasis (PsO) is a common inflammatory skin disease. Besides the skin, it is recognized that this disease can affect multiple domains such as nails, joints and entheses. About 30% of the patients with PsO will develop symptoms in the musculoskeletal domains. Untreated inflammation in psoriatic arthritis (PsA) can lead to irreversible joint damage and further reduces quality of life. Since musculoskeletal involvement is often preceded by the dermatological symptoms of PsO, patients with pure cutaneous psoriasis (PsC) should be routinely screened for joint involvement. Current screening questionnaires, like the often used Psoriasis Epidemiology Screening Tool (PEST), offer a moderate discrimination between patients with PsA and PsC at best. Our aim is to assert the prevalence of known and previously undiagnosed PsA in a PsC cohort. By comparing the gathered data of the PsA and PsC patients, we hope to improve the screening of PsC patients, and to reduce both undertreatment of locomotor symptoms as well as unnecessary diagnostic investigations.

Study objective

To ascertain the prevalence of PsA in a tertiary PsO cohort. Secondary objectives will be to ascertain the clinical features of these patients. With these features we want to find clinical, laboratory or genetic markers to

predict the presence of PsA in PsO patients. Moreover, we wish to establish the added value of PsA screening for the quality of life (QoL) of PsO patients.

Study design

Cross-sectional study with a single follow-up visit after 1 year. Patients will be screened at baseline for PsA symptoms by a rheumatology resident and referred to a rheumatology clinic if deemed necessary. At baseline, several clinical and sociodemographic parameters will be assessed. We will collect blood samples for diverse biochemical studies and genomic DNA. Patients will be followed for 1 year after active screening for PsA. Quality of life (QoL) and treatment change will be recorded after this period, to assess the effect of screening and referral.

Study burden and risks

Baseline screening visit will be performed following a planned usual care outpatient visit. During the screening visit, an oral screening extensive history taking and physical examination will be performed. Questionnaires regarding screening (one) and QoL (three) will be taken. Blood samples will be taken. If treated with systemic therapy, the blood sample can be combined with regular laboratory tests needed for usual care. Patients with suspected PsA will be referrred to the rheumatology clinic of the Sint Maartenskliniek for confirmation of the diagnosis and regular care. After one year, clinical data will be retrieved from both the dermatologic and rheumatic center. Patients will be asked to re-evaluate their QoL. Risks associated with this study are minor. The risk of clinically relevant accidental findings will be discussed thoroughly during the informed consent.

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

* Diagnosis of cutaneous psoriasis
* Age 18 years or above
* Willing and able to comply with visits and study-related procedures
* Provide signed informed consent (IC)

Exclusion criteria

* Age below 18 years
* Unable to give IC
* Unable or unwilling to comply with visits and study-related procedures
* Participation in other trials involving PsO

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-06-2019
Enrollment:	300
Type:	Actual

Ethics review

Approved WMO Date:	29-04-2019
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	24-06-2019
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 21407
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL68137.091.18
OMON	NL-OMON21407