[18F]Fluoride PET-CT in psoriasis patients at risk for developing psoriatic arthritis

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This study has been transitioned to CTIS with ID 2024-514759-13-01 check the CTIS register for the current data. The primary objective of this proof-of-concept study is to investigate the feasibility of whole body [18F]Fluoride PET-CT scans to...

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

Summary

ID

NL-OMON56612

Source
ToetsingOnline

Brief title
Pre-PsA PET

Condition

- Joint disorders
- Epidermal and dermal conditions

Synonym
joint inflammation in skin disease psoriasis, psoriatic arthritis

Research involving
Human

Sponsors and support

Primary sponsor: Amsterdam UMC
Source(s) of monetary or material Support: GRAPPA,Novartis

Intervention

Keyword: Imaging, PET, Psoriatic arthritis

Outcome measures

Primary outcome

The main study endpoint(s)/parameter(s) are the number of individuals with

PET-positive lesions, the distribution of PET-positive lesions and the

quantitative [18F]Fluoride uptake in PET-positive lesions.

Secondary outcome

Secondary outcome is the correlation between PET outcome and development of PsA

in 2 years follow up.

Study description

Background summary

Psoriasis (PsO) is an inflammatory disease that can affect multiple organs, including the skin and joints. These patients experience a substantial clinical burden. In order to prevent long-term structural damage and disability, it is crucial to identify psoriatic arthritis (PsA) as early as possible. Gladman et al showed that patients have an increased prevalence of clinical joint damage progression if they present to a specialist with a symptom duration of more than 2 years, compared to patients with a disease duration shorter than 2 years. Furthermore, patients have a poorer physical function more than 10 years later, despite active treatment, if patients had a symptom duration of more than 1 year before diagnosis. Several other studies confirmed that a shorter disease duration before diagnosis, was associated with better outcomes on the long term.
In most patients (83-87%), the PsO of the skin (hereafter mentioned as PsO) precedes the PsA diagnosis [6], so that could be a window of opportunity for early diagnosis of PsA. However, the prevalence of PsA among patients with psoriasis ranges from 4 to 42% in various studies. This indicates that additional risk factors are needed in order to identify patients that are at risk for the development of PsA. Among patients with PsO or PsA, approximately 40% of them have a family history of these diseases in their first degree relatives.The presence of arthralgia in women, heel pain, fatigue and stiffness

are the earlier symptoms associated with subsequent development of PsA in psoriasis patients. Also the gradual worsening of complaints in those four domains is associated with subsequent development of PsA. This was confirmed by Zaboitti et al, who described that PsO patients with arthralgia were more prone to develop PsA compared to PsO patients without musculoskeletal complaints. It was suggested that PsA is more frequent among patients with severe psoriasis. In a population-based study, 6% of patients with minimal psoriasis had PsA compared with 18% of those with 3-10% body surface area (BSA) and 56% of those with BSA >10%. Psoriatic nail changes have been found to occur more frequently in patients with cutaneous psoriasis who are at higher risk of developing arthritis. It has been shown that the nail is anchored to the skeleton and that subclinical imaging of entheseopathy is common in psoriasis subjects with nail disease but without psoriasis. Nail psoriasis in PsA patients is intimately associated with entheseopathy of the distal interphalangeal joint and that the nail is functionally integrated with the enthesis. In animal models of PsA, the earliest lesion is at the enthesis. Sonographically determined tenosynovitis and enthesitis are the key imaging features present in non-specific PsO arthralgia that are at risk of future PsA development. Studies have shown that psoriasis patients who develop PsA at follow-up have higher enthesitis scores on the ultrasound at baseline, years before developing PsA, which supports the entheses being the key structure in PsA, and the disease may be initiated at the level of the entheses [20, 23]. Zabiotti et al found that sonographically determined tenosynovitis was the only US feature linked to the future evolution of PsA [11]. Faustini et al. confirmed this relationship between subclinical inflammation detected and PsA, highlighting that patients with hands synovitis detected by MRI and arthralgia had 55.5% likelihood to develop PsA within one year [24]. It has been suggested that enthesitis is the primary lesion that underscores the diverse skeletal manifestations of PsA. Simon et al. described that patients with PsO without PsA exhibit enthesiophytes as the result of pathological bone formation in the joints. Bone formation is a pathological hallmark of PsA. The presence of similar changes in patients with psoriasis strongly supports the hypothesis of subclinical joint pathology that antedates the clinical onset of PsA. [18F]Fluoride PET-CT scans might be useful to visualize early axial and peripheral bone formation in the whole body psoriatic patients, as reflection of disease activity, which may be related to a higher risk for development of PsA. [18F]Fluoride uptake represents active bone formation, as fluoride is incorporated into the skeleton at sites of osteoblastic activity.

Study objective

This study has been transitioned to CTIS with ID 2024-514759-13-01 check the CTIS register for the current data.

The primary objective of this proof-of-concept study is to investigate the feasibility of whole body [18F]Fluoride PET-CT scans to detect axial and peripheral neew bone formation in PsA patients taht are at risk to develop

clinically manifest PsA.
The secondary objective is to investigate the correlation between PET outcome and the development of PsA in 2 years of follow up.

Study design

A prospective cohort study in 15 patients with PsO at risk for PsA.

Study burden and risks

The total radiation burden will be about 6.0 mSv.

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

- Psoriasis
- >=1 arthralgia and/or enthesiopathy in >=1 location(s) <= 1 year;
- And >=1 of the following;
- Nail psoriasis
- First-degree relative with PsA
- BSA >=3%

Exclusion criteria

- Other rheumatic disease (such as Axial SpA, RA, SLE, Sjögren)
- Osteoarthritis and/or mechanical explanation of the pain in joints and/or tendons
- Clinically evident arthritis (and/or tenosynovitis)
- Systemic therapy for psoriasis (DMARD, bDMARD)
- Treatment with study medication in the past 3 months
- Pregnancy or breast-feeding

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	21-11-2024
Enrollment:	15
Type:	Actual

Medical products/devices used

Product type:	Medicine

Brand name:	[18F]Fluoride
Generic name:	[18F]Fluoride

Ethics review

Approved WMO Date:	02-03-2023
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	08-02-2024
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
EU-CTR	CTIS2024-514759-13-01
EudraCT	EUCTR2021-001209-57-NL
CCMO	NL77204.029.22