Axial Involvement in Psoriatic Arthritis LUMC

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The overarching aim of the Axial Involvement in Psoriatic Arthritis (AXIS) study is to systematically evaluate clinical and imaging manifestations indicative of axial involvement in patients with PsA to develop classification criteria and a unified...

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

Summary

ID

NL-OMON53984

Source
ToetsingOnline

Brief title
AXIS-LUMC

Condition

- Joint disorders

Synonym
psoriatic arthritis

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: stichting ASAS

Intervention

Keyword: axial skeleton, psoriatic arthritis, spondylitis

Outcome measures

Primary outcome

The frequency of axial involvement in patients with psoriatic arthritis will be expressed as an absolute number and as a percentage based on both local and central assessment.

The burden can be considered to be very low. Information is obtained from patient records or the treating physician at baseline. Patients receive usual care and they will not receive any intervention. Since the nature of this study is observational, and the burden on the participants is very low, there will not be any risks in taking part in this study

Secondary outcome

Frequency of active inflammatory and structural changes on imaging suggestive of inflammatory involvement of axial skeleton (sacroiliac joints and spine) in psoriatic arthritis will be expressed an absolute number and as a percentage;

Study description

Background summary

Involvement of the axial skeleton (of sacroiliac joints and / or spine) is one of the relatively frequent manifestations associated with psoriatic skin disease along with involvement of peripheral musculoskeletal structures (peripheral arthritis, enthesitis, dactylitis), which are usually referred to as psoriatic arthritis (PsA). Data from cohort studies suggest that up to 30% of patients with psoriasis develop PsA. Depending on the definition used, the

prevalence of axial disease varies from 25% to 70% of patients with PsA. Recent data from the CORRONA registry indicated that the presence of axial involvement is associated with a higher likelihood of moderate/severe psoriasis, with higher disease activity and greater effect on quality of life in patients with PsA.

There is an ongoing discussion as to whether patients with psoriasis and inflammatory axial disease should be diagnosed with *PsA with axial involvement* (other commonly used terms: psoriatic spondylitis, psoriatic spondyloarthritis, axial PsA) or with *axial spondyloarthritis with psoriasis*. Although some features typical for axial involvement in PsA have been described (such as asymmetry of inflammatory changes, lower - as compared to the primary axial spondyloarthritis without psoriasis - prevalence of inflammatory back pain and HLA-B27, involvement of the spine without sacroiliac joints), a clear distinction is not always possible due to a natural overlap between these conditions. There is also an overlap between the CASPAR (ClASsification criteria for Psoriatic ARthritis) classification criteria for PsA and ASAS (Assessment of Spondyloarthritis international Society) classification criteria for spondyloarthritis - SpA (both axial and peripheral) resulting from the pathophysiological proximity of the diseases. Currently, there is no clear and widely accepted definition of axial involvement in PsA. Patients with PsA can be classified as patients with axial SpA in the presence of chronic back pain with onset prior to the age of 45 years plus presence of sacroiliitis on magnetic resonance imaging (MRI) or Radiographs (plus one additional SpA feature that can be psoriasis), or alternatively in the presence of HLA-B27 plus 2 additional SpA features. Data from a recent systematic literature suggested that PsA patients with axial involvement frequently have characteristics that would not allow classification of patients as axial SpA such as late onset of back pain, involvement of the spine without sacroiliac joints, weaker association with HLA-B27, less frequent inflammatory character of back pain. Furthermore, it is currently unclear if treatment response in PsA patients with axial involvement can be extrapolated from the data generated in primary axial SpA since only a few studies have been conducted so far in patients with PsA and
(suspected) axial involvement. For example, in primary axial SpA two interleukin-23 inhibitors (ustekinumab and risankizumab) failed to show clinical efficacy compared to placebo, despite good clinical efficacy in psoriasis and PsA with predominant peripheral involvement. There is a need to determine whether these drugs, as well as other drugs that have shown efficacy in peripheral manifestations of PsA are also effective in the axial component of PsA.

In general, axial involvement is poorly assessed (or not assessed at all) in trials with PsA. The main reason for this is the lack of a widely accepted definition of axial involvement in PsA that could be used for research purposes. Since axial involvement may be quite variable and often not present, it has been difficult to justify the added measurement burden and expense of longitudinal MRI assessment of the spine and sacroiliac joints in the whole study population or even in those with presumed axial involvement, which may

vary between study arms. There is an urgent need for criteria and a unified and widely accepted nomenclature for axial involvement in PsA that would allow defining a homogeneous subgroup of patients in the heterogeneous PsA population. In 2018, ASAS and GRAPPA (Group for Research and Assessment of Psoriasis and Psoriatic Arthritis) agreed to develop a consensus definition of axial involvement in PsA to be used for research purposes. In addition to the conducted systematic literature review, an online survey among ASAS and GRAPPA members was conducted in Dec 2018 - Jan 2019 to identify the most relevant variables relevant to deciding on the absence or presence of axial involvement in PsA. The four variables with the highest ranking were related to the objective signs of inflammatory changes in the axial skeleton on Radiographs or MRI.
Currently, there is no PsA cohort in which a complete set of imaging (plain radiographs and MRI of sacroiliac joints and spine) is available in all patients. Therefore, we propose developing a prospective cross-sectional cohort through which classification criteria for axial involvement in PsA can be derived.

Study objective

The overarching aim of the Axial Involvement in Psoriatic Arthritis (AXIS) study is to systematically evaluate clinical and imaging manifestations indicative of axial involvement in patients with PsA to develop classification criteria and a unified nomenclature for axial involvement in PsA that would allow defining a homogeneous subgroup of patients for research.

The main objectives of the planned study are:

1) To determine the frequency of axial involvement in patients with PsA (based on the local and central assessments) in the studied patient population;

2) To identify the frequency of active inflammatory and structural changes on imaging (on MRI and Radiographs) suggestive of inflammatory involvement of axial skeleton (sacroiliac joints and spine) in PsA;

3) To identify factors (clinical, lab, imaging) associated with the presence of axial involvement in PsA (determined based on the local and central assessment).

Study design

This is a cross-sectional study in patients with a definite diagnosis of PsA. Eligible patients will be recruited prospectively and will undergo study-related examinations including imaging (radiography and MRI) of the axial skeleton. These images will be evaluated locally and by the central imaging committee. Collected data will serve as a basis for the determination of the

presence of axial involvement by the local investigator.
patiënts will be asked to come to a research visit, during which a physical examination is performed, a MRI scan is made and the patient will be asked to fill out several questionnaires. 2 sequences of the MRI scan are considered coventional treatment, whereas 2 other extra sequences are part of the study.

Study burden and risks

NA

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

1) Age >= 18 years.
2) Definite diagnosis of PsA.
3) Fulfilment of the CASPAR criteria for PsA.
4) Duration of PsA symptoms <=10 years.
5) Written informed consent.

Exclusion criteria

1) Unable or unwilling to give informed consent or to comply with the protocol.
2) Current or past treatment with biologic or a targeted synthetic disease-modifying antirheumatic drug (DMARDs).
3) Contraindications for MRI and/or plain radiograph examination of sacroiliac joints and spine.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	01-11-2023
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	04-09-2023
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)

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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
ClinicalTrials.gov	NCT04434885
CCMO	NL83283.058.23