Immonotyping target tissues of inflammation in Psoriasis and Psoriatic Artritis

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1. To identify immunological alterations in peripheral lymphoid/skin/synovial tissue of patients with psoriatic artritis and psoriasis2. To correlate these alterations with disease stage, prognosis, treatment response3. To compare immunological...

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

Summary

ID

NL-OMON56005

Source
ToetsingOnline

Brief title
Not applicable

Condition

- Autoimmune disorders
- Joint disorders
- Cornification and dystrophic skin disorders

Synonym
chronic joint inflammation in psoriasis patients

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: VIDI,Europese Unie via IMI HIPPOCRATES (Health initiatives in Psoriasis and PsOriatic arthritis ConsoRTium European States)

Intervention

Keyword: Immunotyping, Psoriasis, Psoriatic artritis

Outcome measures

Primary outcome

1. Frequencies and phenotype of immune cell populations in peripheral lymph nodes (inguinal LNs), skin and joint tissues in psoriatic artritis and psoriasis

2. Differences in immune cell populations profiles (cytokine production, genetic, epigenetic and transcriptional alterations) in peripheral lymph nodes, skin and joint tissues psoriatic artritis and psoriasis

Secondary outcome

1. Frequency and gene expression profiles of stromal cells in lymph nodes of psoriatic artritis and psoriasis patients

2. Frequency and phenotype of immune cells in psoriatic plaque lesions, lymph node and inflamed synovial tissue

3. Gene expression profiles in skin/synovial tissue/lymph node tissue in psoriatic artritis and psoriasis patients

Study description

Background summary

One of the biggest barriers to progress towards better treatment outcomes in psoriatic arthritis (PsA) is 1) the lack of understanding of the disease etiology and mechanisms involved, 2) and the lack of biomarkers that could help

in early (preclinical) diagnosis of the disease. The peripheral lymph nodes (LN) are lymphoid structures that are involved in shaping peripheral immunity. So far it is unknown whether and how these lymphoid structures are involved in PsA pathogenesis, especially in the transition from psoriasis (PsO) to PsA. We hypothesize that peripheral lymphoid tissues are involved in PsA pathophysiology and the lymph nodes display an activation state of immune and stromal cells which plays an important role in the transition from PsO to PsA. We aim to investigate the involvement of the peripheral lymphoid tissue in the immune deregulation that is observed in PsA and PsO patients and compare these to other target tissues such as skin and synovial tissue.

Study objective

1. To identify immunological alterations in peripheral lymphoid/skin/synovial tissue of patients with psoriatic artritis and psoriasis
2. To correlate these alterations with disease stage, prognosis, treatment response
3. To compare immunological alterations in the lymphoid tissues to immunological alterations in psoriatic skin and synovial tissue

The specific types of immunological alterations that we will study include:
• Phenotype and function of T and B cells and innate immune cells
• Cytokine production by innate immune cells and stromal cells
• Genetic, epigenetic and transcriptional alterations of immune cells and stromal cells
• TCR repertoire
• Signaling events in immune cells and stromal cells
• Immunomodulation using stromal cells and/or other cells with regulatory properties

Study design

An investigator initiated cross-sectional study for immune cell characterization and gene expression analysis in skin, lymph node and joint tissues in psoriatic artritis and psoriasis patients.

Study burden and risks

Inguinal lymph node biopsy sampling is well-tolerated. The technology was established at the AMC>10 years ago and has since become a common research tool in rheumatology patients. Inguinal lymph node biopsy is an outpatient procedure which is performed under local anaesthesia and is well tolerated. Skin biopsy is an procedure performed under local anesthesia on regular basis in the dermatology outpatient clinics and is well tolerated. Blood sampling will be conducted in the framework of the routine tests of the patients. Synovial fluid and synovial tissue will be collected from PsA patients with manifested knee,

wrist or ankle joint arthritis or from PsO patients presenting with knee, wrist, MCP-joint or ankle joint arthritis during follow-up. Skin biopsies will be collected from PsO patients with at least one psoriatic plaque skin lesion. Biopsies of skin and lymph node will be repeated in psoriasis and psoriatic artritis patients undergoing therapy with conventional or biological DMARDs, before start of treatment and around minimal four weeks after start of treatment.

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

All patients 18 years or older with a clinical diagnosis of PsO or PsA

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study: • Patients, who are not able to provide informed consent. • History of malignancy • Viral or bacterial infection within the past 4 weeks • Patients using anticoagulant therapy • Present or previous use of systemic corticosteroids less than 28 days before enrollment • Present or previous treatment with any cell depleting therapies, including investigational agents. • Presence of any disease for which study subjects need chronic or intermittent immunosuppressive therapy (e.g. prednisolone). • History of chronic viral infection • Recent (<1 week) bacterial or viral infection • History of autoimmune disease • Recent (< 4 weeks) vaccination

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:	Pending
Start date (anticipated):	01-12-2023
Enrollment:	108
Type:	Anticipated

Ethics review

Approved WMO

Date:	06-11-2023
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
CCMO	NL82026.018.22