

Determining risk factors for the development of psoriatic arthritis (PsA) amongst people living with psoriasis: A patient-driven online prospective European observational cohort

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

Summary

ID

NL-OMON57419

Source

ToetsingOnline

Brief title

HIPPOCRATES Prospective Observational Study (HPOS)

Condition

- Joint disorders
- Epidermal and dermal conditions

Synonym

psoriasis, psoriatic arthritis

Research involving

Human

Sponsors and support

Primary sponsor: Universiteit van Oxford

Source(s) of monetary or material Support: Innovative Medicines Initiative 2 Joint Undertaking (JU) under grant agreement No 101007757

Intervention

Keyword: Observational cohort, Psoriasis, Psoriatic arthritis

Outcome measures

Primary outcome

To identify demographic, clinical and biological predictors for the development of PsA: Development of PsA confirmed by upload of clinic letter confirming diagnosis.

Secondary outcome

To test the performance of the PEST screening questionnaire in identifying PsA: Development of PsA confirmed by upload of clinic letter confirming diagnosis.

To establish the burden of psoriasis across Europe: Patient reported outcomes including PsA impact of disease (PsAID), Multi-dimensional health assessment questionnaire (MD-HAQ), Patient health questionnaire (PHQ-9), FACIT-fatigue.

To establish the burden of psoriasis treatment across Europe: Treatment satisfaction questionnaire for medication (TSQM).

Study description

Background summary

HIPPOCRATES is an Innovative Medicines Initiative (IMI) funded EU Consortium established to address key unmet clinical needs in psoriatic disease. As part of the project, the HIPPOCRATES Prospective Observational Study (HPOS) is a study of patients with psoriasis which will run across Europe. The study will be led by a research team at University of Oxford and supported by a team at University College Dublin. We are aiming to identify people with psoriasis who are at risk of developing psoriatic arthritis. Up to one-third of patients with psoriasis will develop a related arthritis causing inflammation in the joints and tendons.

Study objective

We want to identify which patients will develop arthritis with the long-term and ambitious aim of trying to prevent the development of arthritis before it occurs. As many (most) participants will not develop arthritis, we are also studying the impact of psoriasis on the participants to learn more about how psoriasis affects people's daily lives across Europe.

Study design

We are recruiting/approaching adults with psoriasis and asking study participants to complete questionnaires every 6 months via a dedicated study website. The questionnaires will include a *screening questionnaire* to try to identify arthritis. If participants are identified by the *screening questionnaire* as having possible arthritis, they will be advised to seek local medical help. We will follow up with them to see if they are diagnosed with psoriatic arthritis.

Alongside the questionnaire information from participants, we will ask some participants to provide a blood fingerprick sample using an easy to use at home sampling kit. The blood sample will be posted to a central location (University College Dublin) where it will be stored and then studied in the laboratory to look for markers that may predict the onset of arthritis.

Study burden and risks

Low risk as this is a non-interventional remote study.

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

Adults with psoriasis

Exclusion criteria

Pre-existing diagnosis of psoriatic arthritis

Study design

Design

Study type: Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Basic science

Recruitment

NL
Recruitment status: Pending
Start date (anticipated): 01-11-2024
Enrollment: 1000
Type: Anticipated

Ethics review

Approved WMO
Date: 09-04-2025
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	NL86378.018.24