

# Can we predict which patients with psoriatic arthritis will respond to treatment using precision medicine?

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		<input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 23/03/2021	<b>Overall study status</b> Ongoing	<input checked="" type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 07/05/2026	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data
		<input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Psoriatic arthritis (PsA) is a type of arthritis that affects some people with the skin condition psoriasis. It typically causes affected joints to become swollen, stiff and painful.

PsA is an inflammatory arthritis that develops in around 15% of people with psoriasis, causing swollen and painful joints. For patients who do not respond to standard arthritis drugs, two classes of biologic drugs are available (TNF or IL-17 blockers). A similar proportion of patients respond to both with around 50% achieving a good response. However, we do not know how to predict which patient will respond best to each drug.

Our aim is to test whether we can predict if people with psoriatic arthritis (PsA) will respond to certain biologic drugs using blood tests. We will test if high levels of a type of T cells (activated Th17 cells) or other laboratory tests predict response. We will use statistical tests to estimate how effective these approaches would be for each individual. If successful, this approach could ensure that patients receive their best option first, ensuring their disease is controlled and quality of life improved, while avoiding unnecessary drug use. This is likely to save money for the NHS.

### Who can participate?

Patients aged 18 years or older, with PsA about to start their first biologic treatment will be invited to join the study.

### What does the study involve?

Participants will have a blood sample taken to measure their activated Th17 cells. The patients will be allocated to receive either TNF or IL-17 blocking biologics. We will measure how well they respond after 6 months of treatment and test whether the initial blood test result could have predicted their response.

### What are the possible benefits and risks of participating?

Participants are not expected to benefit directly from participating in the study however they should see an improvement in their PsA symptoms from the treatment they receive. Study visits have been aligned with routine NHS visits to minimise burden and inconvenience but will take

longer and participants will be asked to complete extra questionnaires. Participants will need to have additional blood samples taken which may result in bruising but research samples will be taken at the same time as routine NHS blood tests wherever possible. Participants at 3 sites (Oxford, Glasgow, & St Guys & St Thomas's) will be asked to attend a short additional visit to enable the collection of an additional blood sample. Travel costs will be reimbursed for this additional visit to minimise any financial burden. There are no additional risks from the treatment as the study uses the same treatments that would be prescribed routinely for these patients.

Where is the study run from?  
University of Oxford (UK)

When is the study starting and how long is it expected to run for?  
February 2021 to September 2026

Who is funding the study?  
National Institute for Health Research (NIHR) (UK).

Who is the main contact?  
Dr Laura Coates, [laura.coates@ndorms.ox.ac.uk](mailto:laura.coates@ndorms.ox.ac.uk)

## Contact information

### Type(s)

Scientific, Principal investigator, Public

### Contact name

Dr Laura Coates

### Contact details

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[laura.coates@ndorms.ox.ac.uk](mailto:laura.coates@ndorms.ox.ac.uk)

## Additional identifiers

Integrated Research Application System (IRAS)  
287528

Central Portfolio Management System (CPMS)  
48066

## Study information

## Scientific Title

Optimising Psoriatic Arthritis Therapy with Immunological Methods to Increase Standard Evaluation

## Acronym

OPTIMISE

## Study objectives

A precision choice of bDMARDs in PsA based on lymphocyte cell surface markers guiding selection of either TNF inhibitor or IL17A inhibitor will give superior results to patients having a choice of bDMARD based on clinical characteristics alone.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Approved 24/02/2021, North West - Preston REC (Barlow House, 3rd Floor, 4 Minshull Street, Manchester, M1 3DZ, UK; +44 (0)207 104 8206; Preston.rec@hra.nhs.uk), ref: 21/NW/0016

## Study design

Interventional randomized controlled trial

## Primary study design

Interventional

## Study type(s)

Treatment

## Health condition(s) or problem(s) studied

Arthritis that affects some people with the skin condition psoriasis

## Interventions

All patients will be treated with a biologic drug (TNF inhibitors (adalimumab) or IL-17A inhibitors (secukinumab) in keeping with routine clinical practice. At present both TNF inhibitors and IL-17 inhibitors are licensed and NICE approved as first line biologics in PsA. Patients will be randomised in a 1:1 ratio to receive either TNF or IL-17A inhibitors, stratified by baseline immunophenotype, for 24 weeks.

The TNF inhibitor to be used is adalimumab (any brand) and it is to be given at the usual licensed dose, as per the SmPC:

-The licenced dose of adalimumab for psoriatic arthritis is always 40 mg by subcutaneous injection every 2 weeks, with no loading doses.

The IL-17A inhibitor to be used is secukinumab, brand name Cosentyx, and is to be given at the usual licensed dose as per the SmPC:

-The licensed dose of secukinumab for psoriatic arthritis varies based on the level of baseline skin psoriasis. For patients with concomitant moderate to severe plaque psoriasis, the recommended dose is 300mg by subcutaneous injection with initial dosing at weeks 0, 1, 2, 3 and 4 followed by a monthly maintenance dose. For other patients the recommended dose is 150mg by subcutaneous injection at the same timepoints. This study will follow routine practice and the current label by using the appropriate dose of secukinumab based on the baseline psoriasis

disease activity with the cut off for moderate to severe psoriasis as 10% body surface area. Dose escalation as per the licence is permitted.

### **Intervention Type**

Drug

### **Phase**

Not Applicable

### **Drug/device/biological/vaccine name(s)**

Adalimumab, secukinumab

### **Primary outcome(s)**

Clinical response as measured by the minimal disease activity (MDA) criteria at baseline and week 24

### **Key secondary outcome(s)**

1. Clinical disease pattern at baseline measured by the minimal disease activity (MDA) criteria
2. Immunophenotype data at baseline measuring activated Th17 and intracellular levels of IL-17
3. Activated Th17 proportion and intracellular levels of IL-17 at baseline and week 24
4. Clinical response as measured by the minimal disease activity (MDA) criteria at week 12/16 and week 24
5. Cell-specific transcriptomic data and whole blood transcriptomes from samples collected at baseline and week 24

### **Completion date**

30/09/2026

## **Eligibility**

### **Key inclusion criteria**

Current inclusion criteria as of 15/08/2022:

1. Participant is willing and able to give informed consent for participation in the study
2. Male or female, age 18 years or over
3. Diagnosis of PsA confirmed by the CASPAR criteria
4. Is planned to have biologic therapy for psoriatic arthritis using NICE/SMC criteria (failure of  $\geq 2$  csDMARDs and  $\geq 3$  tender and  $\geq 3$  swollen joints)

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Previous inclusion criteria:

1. Participant is willing and able to give informed consent for participation in the study
2. Male or female, age 18 years or over
3. Diagnosis of PsA confirmed by the CASPAR criteria
4. Is planned to have biologic therapy for psoriatic arthritis using NICE/SMC criteria (failure of  $\geq 2$  csDMARDs and  $\geq 3$  tender/swollen joints)

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

**Age group**

Mixed

**Lower age limit**

18 years

**Upper age limit**

999 years

**Sex**

All

**Total final enrolment**

240

**Key exclusion criteria**

1. Contraindications to either TNF inhibitor or secukinumab:
  - 1.1. History of previous demyelinating disease including multiple sclerosis
  - 1.2. Heart failure (NYHA class 3 or 4)
  - 1.3. Serious infections: active tuberculosis (TB), chronic viral infections (including hepatitis B, C and HIV), recent serious bacterial infections
  - 1.4. Latent TB unless they have received appropriate anti-tuberculous treatment as per local guidelines
  - 1.5. Active symptomatic inflammatory bowel disease
  - 1.6. History of cancer in the last 5 years, other than non-melanoma skin cell cancers cured by local resection or carcinoma in situ
  - 1.7. Hypersensitivity to active ingredient or excipients
2. Current or previous treatment with biologic DMARDs or targeted synthetic DMARDs
3. Use of investigational therapies within 1 month or 5 half-lives (whichever is longer) of baseline
4. Women who are pregnant, lactating or planning pregnancy during the following 12 months

**Date of first enrolment**

01/01/2022

**Date of final enrolment**

31/12/2024

**Locations**

**Countries of recruitment**

United Kingdom

England

Scotland

Wales

**Study participating centre**

**Oxford University Hospitals NHS Foundation Trust**

John Radcliffe Hospital

Headley Way

Headington

Oxford

England

OX3 9DU

**Study participating centre**

**Guy's and St Thomas' Hospitals**

Trust Offices

Guy's Hospital

Great Maze Pond

London

England

SE1 9RT

**Study participating centre**

**Glasgow Royal Infirmary**

10-16 Alexandra Parade

Glasgow

Scotland

G31 2ER

**Study participating centre**

**Midlands Partnership University NHS Foundation Trust**

Trust Headquarters

St Georges Hospital

Corporation Street

Stafford

England

ST16 3SR

**Study participating centre**

**University Hospitals Coventry and Warwickshire NHS Trust**

Walsgrave General Hospital

Clifford Bridge Road

Coventry

England

CV2 2DX

**Study participating centre**  
**Portsmouth Hospitals University NHS Trust**  
Queen Alexandra Hospital  
Southwick Hill Road  
Cosham  
Portsmouth  
England  
PO6 3LY

**Study participating centre**  
**Royal Berkshire NHS Foundation Trust**  
Royal Berkshire Hospital  
London Road  
Reading  
England  
RG1 5AN

**Study participating centre**  
**Royal United Hospitals Bath NHS Foundation Trust**  
Combe Park  
Bath  
England  
BA1 3NG

**Study participating centre**  
**King's College Hospital NHS Foundation Trust**  
Denmark Hill  
London  
England  
SE5 9RS

**Study participating centre**  
**University Hospitals Dorset NHS Foundation Trust**  
Christchurch Hospital  
Fairmile Road  
Christchurch  
England  
BH23 2JX

**Study participating centre**

**Northampton General Hospital NHS Trust**  
Cliftonville  
Northampton  
England  
NN1 5BD

**Study participating centre**  
**South Warwickshire University NHS Foundation Trust**  
Warwick Hospital  
Lakin Road  
Warwick  
England  
CV34 5BW

**Study participating centre**  
**NHS Lanarkshire**  
14 Beckford Street  
Hamilton  
Scotland  
ML3 0TA

**Study participating centre**  
**Liverpool University Hospitals NHS Foundation Trust**  
Royal Liverpool University Hospital  
Prescot Street  
Liverpool  
England  
L7 8XP

**Study participating centre**  
**Sandwell and West Birmingham Hospitals NHS Trust**  
Midland Metropolitan University Hos  
Grove Lane  
Smethwick  
England  
B66 2QT

**Study participating centre**  
**North Middlesex University Hospital**  
Sterling Way  
London

England  
N18 1QX

**Study participating centre**

**NHS Forth Valley**

33 Spittal Street

Stirling

Scotland

FK8 1DX

**Study participating centre**

**Leeds Teaching Hospitals NHS Trust**

Chapel Allerton Hospital

Chapeltown Road

Leeds

England

LS7 4SA

**Study participating centre**

**Sheffield Teaching Hospitals NHS Foundation Trust**

Royal Hallamshire Hospital

Glossop Road

Sheffield

England

S10 2JF

## **Sponsor information**

**Organisation**

University of Oxford

**ROR**

<https://ror.org/052gg0110>

## **Funder(s)**

**Funder type**

Government

## Funder Name

NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC); Grant Codes: NIHR129023

## Funder Name

National Institute for Health Research (NIHR) (UK)

## Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

## Funding Body Type

Government organisation

## Funding Body Subtype

National government

## Location

United Kingdom

# Results and Publications

## Individual participant data (IPD) sharing plan

The participant-level data set and statistical code will be available upon reasonable request from Laura Coates (laura.coates@ndorms.ox.ac.uk) and the Oxford Clinical Trials Research Unit (OCTRU; octrutrialshub@ndorms.ox.ac.uk) once the study findings have been published in full and for as long as this data is useful. Consent has been provided consent to share with the funder and other researchers based at hospitals, universities, non-profit institutions or commercial laboratories worldwide; however, some specific data items may not be shared in order to maintain participant anonymity.

## IPD sharing plan summary

Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>		28/03/2023	29/09/2023	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Protocol file</a>	version 8.0	07/11/2023	08/11/2023	No	No
<a href="#">Protocol file</a>	version 10.0	04/11/2025	23/01/2026	No	No
<a href="#">Protocol file</a>	version 11.0	26/03/2026	31/03/2026	No	No
<a href="#">Statistical Analysis Plan</a>	version 1.0	21/04/2026	07/05/2026	No	No