

# PLAN-psoriasis feasibility trial

<b>Submission date</b> 26/01/2024	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 13/02/2024	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 09/05/2025	<b>Condition category</b> Skin and Connective Tissue 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

More severe psoriasis is often treated with injection medicines called 'biologics', which target the immune system. Biologics are very effective at clearing psoriasis. People who have clear /nearly clear psoriasis currently take their treatment continuously and indefinitely. This can be burdensome (e.g. regular injections, hospital follow-up, drug side-effect risks including infections) and expensive. Personalised treatment plans may allow individuals to take the lowest amount of biologic needed to keep their psoriasis well-controlled. This would benefit patients and the NHS by reducing the risks and burden of treatment. The PLAN-psoriasis feasibility trial is investigating whether it is practical and acceptable (to patients, and healthcare professionals) to use personalised biologic treatment plans. The study will determine how feasible personalised treatment plans are for routine care. Findings will be used to design a larger study to look at the effectiveness of personalised treatment plans for the management of psoriasis.

### Who can participate?

Adults (aged 16 years old and over) with psoriasis who have had clear or nearly clear skin for 12 months or longer on their biologic treatment (risankizumab).

### What does the study involve?

Participants will be allocated, by chance, to one of three treatment plans for 12-months:

1. Patient-led 'as needed' treatment: participants stop their biologic, and re-start it at the first sign of psoriasis appearing.
2. Therapeutic drug monitoring guided treatment: the concentration of drug in the blood is used to calculate how often participants inject their biologic.
3. Standard care: continue biologic treatment at the standard dose.

Participants will complete three-monthly online questionnaires about their skin, quality of life and mood, and take photographs of their skin. Blood tests will be taken at study visits at the study start and end. A self-taken blood sample will be arranged at 6-months. Participants can organise a face-to-face 'ad hoc' visit if they are concerned their psoriasis is worsening or if they are experiencing issues related to their psoriasis or treatment. Some will be invited to participate in an optional recorded interview about their experiences of the study.

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

Possible benefits:

Participants may benefit from stopping or taking a lower dose of their biologic treatment. It may involve fewer injections and hospital follow-up visits, and they may experience fewer side effects of the medication. Some people find it rewarding to take part in medical research and appreciate the additional contact with the study team.

Involvement in the study will help to inform future research into treatment recommendations for people with psoriasis. The information and blood samples collected in the study can be used by the scientific community to understand psoriasis biology and treatment responses to improve the health and well-being of people with psoriasis.

Possible disadvantages:

Changing how often biologic injections are taken may increase the risk of a psoriasis flare. However, all participants will be closely monitored and if they report any flaring of psoriasis or concerns, an ad hoc follow-up face-to-face visit with our study doctors will take place quickly (within 5 working days), and their treatment may be adjusted if necessary. Participants will be asked to give up some of their time to attend study visits and complete study questionnaires and other study procedures (e.g. take photos of skin and donate blood samples). Blood tests can be uncomfortable and can cause some bruising or lightheadedness. On very rare occasions, infections can arise as a result of having blood taken. We will always try to take research blood samples when routine blood tests are taken.

Where is the study run from?

St John's Institute of Dermatology, King's College London  
Guy's and St Thomas' NHS Foundation Trust

When is the study starting and how long is it expected to run for?

July 2023 to September 2026

Who is funding the study?

1. National Institute for Health and Care Research (NIHR)
2. National Psoriasis Foundation

Who is the main contact?

Dr Satveer Mahil, [PLAN@kcl.ac.uk](mailto:PLAN@kcl.ac.uk)

**Study website**

<https://stjohnsresearch.org/plan>

## Contact information

**Type(s)**

Public, Scientific, Principal Investigator

**Contact name**

Dr Satveer Mahil

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**Contact details**

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## Additional identifiers

### EudraCT/CTIS number

Nil known

### IRAS number

335278

### ClinicalTrials.gov number

Nil known

### Secondary identifying numbers

CPMS 60537, IRAS 335278, protocol number: EDGE 161885

## Study information

### Scientific Title

Patient-led 'as needed' treatment vs therapeutic drug monitoring guided treatment vs continuous treatment for psoriasis: a UK multicentre assessor-blind, parallel-group, open-label randomised controlled feasibility trial

### Acronym

PLAN-psoriasis feasibility trial

### Study objectives

Personalised biologic dose minimisation treatment strategies are practical and acceptable for people with well controlled psoriasis (clear or nearly clear skin) in routine care.

This study will assess the feasibility of (i) patient-led 'as needed' treatment, i.e. stop biologic treatment and re-start it at the first sign of psoriasis appearing, and (ii) therapeutic drug monitoring (TDM) guided treatment, whereby the concentration of drug in blood (measured using a blood test) is used to calculate how often the biologic injection is taken, in comparison to (iii) standard care (continuous biologic treatment).

### Ethics approval required

Ethics approval required

### Ethics approval(s)

Approved 26/02/2024, Seasonal REC (Health Research Authority) (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8129; seasonal.rec@hra.nhs.uk), ref: 24/LO/0089

### Study design

Multicentre assessor-blind parallel-group open-label randomized controlled feasibility trial (Non-CTIMP)

### **Primary study design**

Interventional

### **Secondary study design**

Randomised controlled trial

### **Study setting(s)**

Home, Hospital, Internet/virtual, Medical and other records, Telephone

### **Study type(s)**

Treatment

### **Participant information sheet**

Not available in web format, please use the contact details to request a patient information sheet

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

Psoriasis being treated with biologic therapy and has been clear/nearly clear for at least 12 months

### **Interventions**

The PLAN-psoriasis feasibility trial is a multi-centre, assessor-blind, parallel-group, open-label, randomised controlled feasibility trial comparing the practicality and acceptability (to patients and healthcare professionals) of two dose-minimisation biologic treatment plans versus standard care (continuous biologic treatment) in adults with psoriasis who have had clear/nearly clear psoriasis on biologic treatment for at least 12 months.

The two-dose minimisation treatment plans are:

1. Patient-led 'as needed' treatment: participants stop their biologic treatment, and restart it at the first sign of psoriasis appearing.
2. Therapeutic Drug Monitoring (TDM) guided treatment: the dose of each participant's biologic treatment is calculated based on the concentration of the drug in their blood (measured using a blood test).

### **Recruitment to the study**

A member of the research team will approach potential participants and discuss the study with them. They will be provided with the communication material, including the participant information sheet and study team contact details, via a letter/email/text/phone whichever is most appropriate. Potential participants will be given an appropriate amount of time to consider their participation in the study and the opportunity to ask questions. If they wish to participate, and they are eligible, a trained member of the research team will obtain written informed consent or eConsent, as appropriate. We will recruit 90 participants in total.

### **Study schedule**

#### **1. Screening visit**

The research team at the study site will confirm the participant is suitable to take part in the study, register the participant on the study databases and collect a blood sample

## 2. Baseline visit

- The research team at the study site will collect some basic information about the participant's psoriasis, general health and the medications they are taking. They will also perform a skin examination to assess psoriasis.
- At this point, the participant is randomised (allocated by chance), using the bespoke King's Clinical Trials Unit (KCTU) randomisation system to one of the three treatment plans (i. patient-led 'as-needed' treatment, ii. TDM-guided dosing treatment, or iii. standard care/continuous treatment) and asked to follow this treatment plan for 12 months.
- Participants will be asked to complete self-reported outcomes in the online mySkin portal about their psoriasis, quality of life, mood and daily function. They will also be asked to upload photos of their skin so that we can assess how active their psoriasis is over time.

## 3. Follow-up data collection

Every three months during the study (months 3, 6, 9 and 12) all participants will be asked to complete self-reported outcomes in the online mySkin self-report portal about their skin, quality of life, mood and daily function, as well as upload photos of their skin.

## 4. 6-month blood sample

At 6 months, we will ask all participants for a blood sample. They will be asked to take the sample themselves at home using a finger prick test.

## 5. Ad hoc Patient-Initiated Follow-Up: PIFU

No matter which treatment plan participants are on, they can request a face-to-face visit with the research team at the study site at any time during the study in the event of self-assessed (Patient Global Assessment) moderate or worse psoriasis or concerns about any intercurrent issues. They can request the visit via the secure online mySkin portal (with self-taken photos) and the research team will see them within 5 working days.

During the PIFU visit, treatment will be instigated according to clinical need including reinstatement of standard dosing interval (as appropriate, for those in the intervention arms) until disease control is recaptured, dose escalation, adjunctive therapy, or treatment switch. They will also be asked for a blood sample.

## 6. Final study visit (12 months)

- At the end of the study (12 months), participants will have a face-to-face visit with a member of the research team at the study site. The person assessing their skin will not know which treatment plan they are on to ensure a fair and unbiased comparison between the three treatment plans.
- Participants will be asked to complete the final set of self-report outcomes and upload photos of their skin on the mySkin portal.
- Participants will be asked for a final blood sample.

**7. Nested qualitative study** A subset of participants (at least 8 per interventional treatment plan) and healthcare professionals (at least 8) will be invited to take part in an interview (at study exit) about their participation in the study. The interview will either take place face-to-face or via videoconference at a time and place suitable for the participant. This is optional and participants who agree to take part will sign a separate consent form (or eConsent, as appropriate) for this.

## Intervention Type

Mixed

## **Primary outcome measure**

1. Practicality and acceptability is a composite outcome, forming the decision to progress to full RCT, based on a range of parameters including the following, at 12 months:
  - 1.1. Recruitment rate measured using the proportion of eligible individuals invited to participate who are randomised (overall) in study records
  - 1.2. Retention measured using the proportion of participants completing the 12-month follow-up visit (overall) in study records
  - 1.3. Adherence to the treatment strategy by patients and clinicians measured using questionnaires
  - 1.4. Acceptability of the treatment strategy to patients and clinicians measured using questionnaires and qualitative interviews with a subset of participants

## **Secondary outcome measures**

1. Clinical effectiveness is measured as follows:
  - 1.1. Number of weeks per patient spent with 'disease control'. 'Disease control' is defined as Patient Global Assessment clear/nearly clear skin with no disease worsening. It is assessed 3-monthly via the mySkin online self-report platform/app and at in-person visits (month 12 and any PIFU). 'Disease worsening' is defined as an assessor blind increase of at least 3 in PASI from study entry and minimum PASI 5 and/or a treatment change (biologic dose escalation, biologic switch, or adjunctive therapy). Disease worsening is assessed at in-person visits (month 12 and any PIFU).
  - 1.2. Number of disease worsening episodes per patient (see definition of disease worsening above).
  - 1.3. Disease severity at the end of the trial measured using assessor-blind skin assessments at the month 12 visit i.e. PASI and Physician Global Assessment.
  - 1.4. Quality of life, measured using the Dermatology Life Quality Index (DLQI) and 5-level EQ-5D (EQ-5D-5L).
  - 1.5. Itch, measured using the Itch Numeric Rating Scale.
  - 1.6. Depression and anxiety, measured using the Patient Health Questionnaire (PHQ) for depression and Generalised Anxiety Disorder (GAD).
  - 1.7. Illness perception, measured using the Brief Illness Perception Questionnaire (BIPQ).
  - 1.8. Psoriatic arthritis disease impact (if the participant has a rheumatologist-confirmed diagnosis of psoriatic arthritis), measured using the Psoriatic Arthritis Impact of Disease (PsAID) questionnaire.
2. Treatment/healthcare burden is measured using records as follows:
  - 2.1. Total drug exposure, measured using the number of biologic injections administered per patient
  - 2.2. Number of drug-free weeks per patient (post 12-week cycle)
  - 2.3. Total number of PIFU visits
3. Safety/tolerability is measured using records as follows:
  - 3.1. Incidence of adverse events and serious infections.
  - 3.2. Incidence of new-onset psoriatic arthritis (screened for using the Psoriasis Epidemiology Screening Tool, PEST) or flare of psoriatic arthritis, as confirmed by a rheumatologist.
  - 3.3. Proportion of patients with anti-drug antibodies.
  - 3.4. Number of injection site reactions
4. Feasibility of collecting data on healthcare costs and resource use for each of the treatment strategies i.e. proportion of missing data, measured using study data at 12 months
5. Acceptability and practicality of follow-up completion measured using study data, assessed by

the proportion of participants who submitted complete 3-monthly self-assessments [including photos] via the mySkin online platform/app; the proportion of missing data per participant; the length of in-person study visits [month 12 visit, PIFU]

**Overall study start date**

01/07/2023

**Completion date**

01/09/2026

## Eligibility

**Key inclusion criteria**

1. Adults (16+) with a diagnosis of chronic plaque psoriasis who have clinician (Physician Global Assessment) and patient (Patient Global Assessment) assessed clear/nearly clear skin at study entry on self-administered IL-23p19 inhibitor risankizumab biologic monotherapy.
2. Evidence of clear/nearly clear skin on risankizumab monotherapy for  $\geq 12$  months before study entry.
3. Clinician-assessed PASI  $\leq 2$  on study entry.
4. Capacity to provide fully informed consent to participate.
5. Willing and able to comply with scheduled visits, treatment plan, and other study procedures.

**Participant type(s)**

Patient

**Age group**

Mixed

**Lower age limit**

16 Years

**Sex**

Both

**Target number of participants**

Planned Sample Size: 90; UK Sample Size: 90

**Key exclusion criteria**

1. Adults receiving risankizumab primarily for psoriatic arthritis. Those receiving biologic therapy primarily for psoriasis and with controlled arthritis (no active joints or entheses) can be included.
2. Any medical condition that, in the opinion of the investigator, may compromise the safety of the participant in the trial, compromise the evaluation of the trial outcomes, or reduce the participant's ability to participate in the trial (e.g. where loss of control of psoriasis may be a risk to an individual's future psoriasis management such as those with a history of unstable psoriasis or generalised pustular psoriasis).
3. Concomitant immune-modifying therapy or phototherapy.
4. Currently participating in another interventional clinical trial.
5. Inability to give written informed consent.

**Date of first enrolment**

18/11/2024

**Date of final enrolment**

30/06/2025

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Guy's and St Thomas' NHS Foundation Trust**

Great Maze Pond

London

United Kingdom

SE1 9RT

**Study participating centre**

**Epsom and St Helier University Hospitals NHS Trust**

St Helier Hospital

Wrythe Lane

Carshalton

United Kingdom

SM5 1AA

**Study participating centre**

**The Newcastle upon Tyne Hospitals NHS Foundation Trust**

Freeman Hospital

Freeman Road

High Heaton

Newcastle upon Tyne

United Kingdom

NE7 7DN

**Study participating centre**

**Northern Care Alliance NHS Foundation Trust**

Salford Royal

Stott Lane

Salford

United Kingdom

M6 8HD



**Study participating centre**

**Kingston Hospital NHS Foundation Trust**

Galsworthy Rd  
Kingston upon Thames  
United Kingdom  
KT2 7QB

**Study participating centre**

**Lewisham and Greenwich NHS Trust**

University Hospital Lewisham  
Lewisham High Street  
London  
United Kingdom  
SE13 6LH

**Study participating centre**

**Barts Health NHS Trust**

The Royal London Hospital  
80 Newark Street  
London  
United Kingdom  
E1 2ES

**Study participating centre**

**Royal Berkshire NHS Foundation Trust**

Royal Berkshire Hospital  
London Road  
Reading  
United Kingdom  
RG1 5AN

**Study participating centre**

**University Hospitals Bristol and Weston NHS Foundation Trust**

Trust Headquarters  
Marlborough Street  
Bristol  
United Kingdom  
BS1 3NU

**Study participating centre****The Dudley Group NHS Foundation Trust**

Russells Hall Hospital

Pensnett Road

Dudley

United Kingdom

DY1 2HQ

**Study participating centre****East Suffolk and North Essex NHS Foundation Trust**

Colchester Dist General Hospital

Turner Road

Colchester

United Kingdom

CO4 5JL

**Study participating centre****University Hospitals Sussex NHS Foundation Trust**

Worthing Hospital

Lyndhurst Road

Worthing

United Kingdom

BN11 2DH

**Study participating centre****Royal Devon University Healthcare NHS Foundation Trust**

Royal Devon University NHS Ft

Barrack Road

Exeter

United Kingdom

EX2 5DW

**Sponsor information****Organisation**

King's College London

**Sponsor details**

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WC2B 4LL  
+44 (0)2078487306  
vpri@kcl.ac.uk

**Sponsor type**

Hospital/treatment centre

**Website**

<https://www.kcl.ac.uk/research/home>

**ROR**

<https://ror.org/0220mzb33>

## **Funder(s)**

**Funder type**

Government

**Funder Name**

National Institute for Health and Care Research

**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

**Funder Name**

National Psoriasis Foundation

**Alternative Name(s)**

National Psoriasis Foundation, Inc., NPF

**Funding Body Type**

Government organisation

**Funding Body Subtype**

Trusts, charities, foundations (both public and private)

**Location**

United States of America

## Results and Publications

**Publication and dissemination plan**

The results of the study will be reported and disseminated widely to all stakeholders through international clinical and scientific conferences, in peer-reviewed scientific journals, and engagement with the public and patient community including via networks of the Psoriasis Association, NIHR and National Psoriasis Foundation.

**Intention to publish date**

30/09/2027

**Individual participant data (IPD) sharing plan**

The data sharing plans for the current study are unknown and will be made available at a later date

**IPD sharing plan summary**

Data sharing statement to be made available at a later date