ISRCTN17922845 https://doi.org/10.1186/ISRCTN17922845

PLAN-psoriasis feasibility trial

Submission date	Recruitment status	[X] Prospectively registered
26/01/2024	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
13/02/2024	Ongoing	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
09/05/2025	Skin and Connective Tissue Diseases	[X] 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

Study website
https://stjohnsresearch.org/plan

Contact information

Type(s)
Public, Scientific, Principal Investigator

Contact name
Dr Satveer Mahil

ORCID ID
http://orcid.org/0000-0003-4692-3794

Contact details
Consultant Dermatologist and Reader, St John's Institute of Dermatology, 9th Floor Tower Wing, Guy's Hospital, Great Maze Pond

London
United Kingdom
SE1 9RT
-
PLAN@kcl.ac.uk

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 ≥12 months before study entry.
3. Clinician-assessed PASI ≤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
Room 8.11, 8th Floor Melbourne House, 44-46 Aldwych
London
England

United Kingdom
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