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Trial to investigate the benefits of two drugs, adalimumab and methotrexate, in treating patients with moderate psoriasis

Submission date
08/05/2026

Recruitment status
Recruiting

Registration date
07/07/2026

Overall study status
Ongoing

Last Edited
05/08/2026

Condition category
Skin and Connective Tissue Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Psoriasis is a long-term skin condition that causes red, scaly, and sometimes painful patches on the skin. It affects about 3% of people in the UK and can have a major impact on daily life and wellbeing. For many years, one of the main treatments has been methotrexate (MTX), taken as tablets or injections. Although MTX can help, it requires regular blood tests because it can sometimes affect the liver or bone marrow. In the last 15 years, newer treatments called biologics have become available. These are injections that block the signals in the immune system that cause psoriasis. The most commonly used biologic is adalimumab (ADA). At the moment, ADA is only offered to people with severe psoriasis because there is not enough research showing whether it works better than MTX for people with moderate psoriasis. ADA also tends to cause fewer side effects and usually requires far fewer clinic visits. This study aims to compare ADA and MTX to see which treatment helps more people achieve a major improvement in their skin. A 75% improvement in psoriasis severity is the internationally recognised standard for a meaningful response, as patients who reach this level usually notice a significant benefit in their daily lives. If ADA is shown to work better than MTX for moderate psoriasis, the results could influence future NICE guidance and potentially improve treatment options for many patients. The study will also look at the cost of each treatment and how they affect quality of life.

Who can participate?
Patients aged 18 years and over with moderate chronic plaque psoriasis

What does the study involve?
Participants will be randomly assigned to receive either weekly MTX injections or ADA injections every 2 weeks. After 16 weeks, their skin improvement will be assessed and the two treatments compared.

What are the possible benefits and risks of participating?
The time to attend visits may be an additional burden for participants, as this is potentially longer than would be required for standard care, particularly for the adalimumab group. For

those in the methotrexate group, the study may involve fewer visits than study locations might usually do as standard. The possibility for ad hoc visits is therefore built into the protocol to allow for additional visits if required, in line with this type A, pragmatic trial. Visits will be restricted to those necessary for the study and can be flexibly scheduled in a ±2-week window. Travel expenses are reimbursed, and homecare delivery and self-injection are used (self-injection is standard for these drugs in usual clinical practice) to avoid repeated travel.
Study procedures are an additional burden for participants; these are clinical examinations and assessments, blood tests, chest X-rays, pregnancy testing, and research blood samples. These are limited to what is necessary, however.
Study treatments represent a further burden; these are self-injection, management of IMP supplies, diary and questionnaire completion and, for methotrexate participants, higher frequency of injections, potential folic acid supplementation and increased monitoring. However, this does mirror standard practice, and training will be provided to participants, as per site standard practice, in self-administering injections.
Potential physical and emotional burdens include side effects, disease flare-ups, blood draw discomfort, and awkward feelings around not revealing trial treatment to the observer. These are well-known and frequently used drugs with a well-known safety profile.
Lifestyle burdens include female participants committing to not becoming pregnant during the trial due to the potential risk of taking IMP during pregnancy. Participants will be made aware of this in the Participant Information Sheet.
X-ray exposure carries a small risk of developing cancer due to the ionising radiation involved, which can damage DNA. However, the benefits of X-rays for diagnosing and treating medical conditions generally outweigh these risks. A typical chest X-ray exposes a patient to about 0.1 mSv of radiation, roughly equivalent to natural background radiation exposure over 10 days. Participants are made aware of this risk in the Participant Information Sheet.

Where is the study run from?
Newcastle Clinical Trials Unit (UK)

When is the study starting and how long is it expected to run for?
May 2026 to October 2029

Who is funding the study?
Health Technology Assessment Programme (UK)

Who is the main contact?
Study inbox: methormab@newcastle.ac.uk

Contact information

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Scientific, Public

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Additional identifiers

Integrated Research Application System (IRAS)
1013551

Central Portfolio Management System (CPMS)
66387

Sponsor's protocol code number
11105

Study information

Scientific Title
An observer blind randomised controlled trial to compare the clinical and health economic benefits of prescribing adalimumab instead of methotrexate in patients with moderate psoriasis with psoriasis area and severity index (PASI) scores of ≥5 and <10

Acronym

METHorMAB

Study objectives
METHorMAB will investigate the clinical effectiveness and cost-effectiveness of adalimumab (ADA) and methotrexate (MTX) in patients with PASI ≥5 and <10 who currently cannot use ADA under NHS rules. It is hypothesised that in this group of patients, ADA will be superior to MTX. Patients with PSO with PASI >5 and ≤10 are often extremely impacted by their disease, with a PASI of 8 or 9 functionally similar to PASI 10. Work with our PPIE groups confirmed that this group of patients with moderate psoriasis has not been looked after well due to a lack of clinical trials investigating evidence for the benefit of biologic medication in the PASI >5 and ≤10 severity.

1. To measure the change in severity and extent of psoriasis over time
2. To measure severity and extent of psoriasis over time
3. To measure quality of life over time
4. To examine drug survival
5. To assess overall disease severity
6. To assess acceptability of the interventions
7. To assess compliance and adherence to treatment
8. To assess serious infection, major cardiovascular disease, death

Secondary economic objectives:
1. To assess average healthcare costs to manage those with moderate psoriasis
2. To assess average utility scores
3. To assess average QALYs per participant
4. To compare the cost-effectiveness of adalimumab versus methotrexate in adult patients with psoriasis at 12 months

Ethics approval required
Ethics approval required

Ethics approval(s)
Submitted 08/05/2026, South Central – Berkshire B REC (Health Research Authority, -, -, United Kingdom; -; berkshireb.rec@hra.nhs.uk), ref: 26/SC/0155

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Active

Assignment
Parallel

Purpose

Treatment

Study type(s)
Efficacy, Treatment, Other

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

Interventions
1. 80 mg loading, then 1 week later, and subsequently 2-weekly throughout the trial, 40 mg adalimumab subcutaneous injections (intervention)
2. Weekly 17.5 mg methotrexate subcutaneous injections (control)

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Adalimumab, methotrexate

Primary outcome(s)
Primary clinical end point:
The proportion of participants achieving a 75% improvement in their psoriasis area and severity score (PASI 75) at 16 weeks compared to baseline

Primary economic end point:
Incremental cost per quality-adjusted life year (QALY) gained at 24 weeks, based on EQ-5D-5L collected at baseline, 16 and 24 weeks and Service Use Questionnaire (SUQ) collected at baseline and 24 weeks

Key secondary outcome(s)
1. The proportion of participants achieving a 75% improvement in their psoriasis area and severity score (PASI 75), measured using the Psoriasis Area and Severity Index (PASI) score at baseline and 24 weeks
2. The proportion of participants achieving a 90% improvement in their psoriasis area and severity score (PASI 90), measured using the Psoriasis Area and Severity Index (PASI) score at baseline, 16 and 24 weeks
3. The proportion of participants achieving a 100% improvement in their psoriasis area and severity score (PASI 100), measured using the Psoriasis Area and Severity Index (PASI) score at baseline, 16 and 24 weeks
4. PASI score as a continuous variable measured using the Psoriasis Area and Severity Index (PASI) score at baseline, 16 and 24 weeks
5. Proportion of participants achieving absolute PASI measured using the Psoriasis Area and Severity Index (PASI) score at baseline, 16 and 24 weeks
6. Proportion of participants achieving Dermatology Life Quality Index (DLQI) 0 or 1 measured using the Dermatology Life Quality Index (DLQI) score at baseline, 16 and 24 weeks
7. DLQI score as a continuous variable measured using the Dermatology Life Quality Index (DLQI) score at baseline, 16 and 24 weeks
8. Number of participants on trial drug, noted at trial visits at 16 and 24 weeks

9. Number of days on drug, noted at trial visits throughout the trial
10. Overall disease severity and acceptability of interventions measured using the Physician Global Assessment (PGA) for psoriasis score at baseline, 16 and 24 weeks
11. Missed injections at study visits recorded throughout the trial
12. Rates of serious infection, major cardiovascular disease, death, noted at trial visits throughout the trial
13. Average healthcare costs to manage moderate psoriasis patients measured using Service Use Questionnaires (SUQ), EQ-5D-5L and PASI questionnaires at baseline, 16 and 24 weeks
14. Average utility scores: extrapolation of costs and QALYs from data observed during the trial throughout the trial

Completion date
31/10/2029

Eligibility

Key inclusion criteria
1. Adults aged ≥ 18 years of age with a diagnosis of moderate chronic plaque psoriasis, as defined by PASI score ≥5 and <10
2. Able and willing to provide written informed consent
3. Able to self-administer subcutaneous therapy
4. Willing to use effective contraception if woman of childbearing potential

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
100 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Treatment with methotrexate or adalimumab within 6 months prior to randomisation
2. Prior use of any biologic therapy for psoriasis, psoriatic arthritis, inflammatory bowel disease, or other inflammatory joint diseases
3. Patients who are currently receiving phototherapy, have received phototherapy within the 4 weeks prior to randomisation, or who will require phototherapy during the trial treatment period are excluded.
4. Topical treatment except emollients and mild topical steroids within 2 weeks prior of randomisation*

5. Use of other systemic drugs for the treatment of psoriasis within 12 weeks prior of randomisation*
6. Actively attempting to conceive, are pregnant, or breastfeeding
7. Male participants trying to conceive
8. Co-existing health problems that contraindicate immunosuppression, including tuberculosis (TB), chronic viral infectious diseases, active malignancy
9. Any conditions associated with worsening due to TNF inhibition including multiple sclerosis personal history or in a first-degree relative, personal history of lupus, personal history of moderate or severe heart failure
10. Patients with a significant current neuropsychiatric illness; or any lifetime history of suicidal ideation, suicidal behaviour, or suicide attempts; or are clinically deemed to have an elevated suicide risk by the investigator.

*Patients will be allowed to use emollients and mild topical steroids such as hydrocortisone or clobetasone butyrate (Eumovate) throughout trial inclusion. Stronger topical steroids such as betamethasone (including the use of dovobet) or calcineurin antagonists (such as topical tacrolimus or phototherapy) are not permitted. A 2-week washout period will be needed for stronger topical treatments** and 12 weeks for other systemic drugs for PSO.

**Tacrolimus ointment 0.1% or 0.03% will be allowed as a rescue medication for facial psoriasis if needed.

Date of first enrolment
01/09/2026

Date of final enrolment
01/03/2028

Locations

Countries of recruitment
United Kingdom

Study participating centre
-
-
-
England
-

Sponsor information

Organisation
Newcastle Clinical Trials Unit

Funder(s)

Funder type

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date