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A study investigating whether Bimekizumab can reduce liver inflammation in people with psoriatic disease

Submission date
14/05/2026

Recruitment status
Recruiting

Registration date
14/07/2026

Overall study status
Ongoing

Last Edited
30/07/2026

Condition category
Other

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

Plain English summary of protocol

Background and study aims
People with psoriasis and psoriatic arthritis (psoriatic disease) are at increased risk of developing liver disease, including non-alcoholic fatty liver disease, also known as metabolic dysfunction-associated steatotic liver disease (MASLD). Liver problems may affect general health and quality of life and can also make treatment of psoriatic disease more difficult. Previous research by the study team suggests that newer treatments for psoriatic disease, such as Bimekizumab, may help improve liver health.

This study aims to investigate the effect of Bimekizumab on liver inflammation and scarring in people with psoriatic disease using a new non-invasive MRI scanning technique. The study will recruit 30 participants who are about to start Bimekizumab as part of their routine care. Participants will undergo MRI scans before starting treatment and again around 6 months later. The scans will mainly assess the liver, but will also provide information about other organs including the heart, lungs, kidneys, pancreas and spleen. The study will also collect information about participants' psoriatic disease symptoms to better understand how Bimekizumab works in the body.

Who can participate?
Adults aged 18 years and over with psoriasis or psoriatic arthritis who are due to start Bimekizumab treatment as part of their routine clinical care. Participants must be willing and able to undergo MRI scans before and after starting treatment.

What does the study involve?
The study involves up to four visits.
At the screening visit, participants will provide informed consent, undergo eligibility assessments, complete questionnaires about their health and psoriatic disease symptoms, and provide blood samples. Participants will also be given a stool sample collection kit and diet questionnaire to complete at home and return by post.
Participants will undergo an MRI scan before starting Bimekizumab treatment. The date Bimekizumab treatment begins (baseline/Day 0) will be recorded as part of the study, although

no additional clinic visit is required for this.
Around 24 weeks after treatment begins, participants will attend a follow-up visit where health assessments, questionnaires and blood tests will be repeated. Participants will also complete a second stool sample collection and diet questionnaire.
A second MRI scan will be performed around 24 weeks after starting Bimekizumab to assess changes in the liver and other organs. Where possible, study visits and MRI scans will be scheduled on the same day to reduce the number of visits required.

What are the possible benefits and risks of participating?
There may be no direct benefit from taking part in this study. However, participants will undergo two MRI scans that would not normally be performed as part of routine care. These scans may identify changes suggestive of liver disease or other abnormalities. Information gained from this study may also help improve understanding and future treatment of liver disease in people with psoriatic disease.

Taking part in the study will involve additional time at clinic visits for study assessments and questionnaires. Blood samples taken as part of the study may cause temporary discomfort, bruising or, rarely, fainting. Wherever possible, research blood samples will be taken at the same time as routine NHS blood tests.

Bimekizumab is prescribed as part of routine NHS care for psoriasis and psoriatic arthritis. As with any medication, there are potential side effects and risks associated with treatment, which participants should discuss with their treating doctor.

MRI scans are considered safe and do not involve exposure to ionising radiation (x-rays). However, MRI scanning is not suitable for everyone because it uses a strong magnet. Participants will undergo safety screening before the scan, particularly if they have certain metal implants, medical devices or metal fragments in the body.

There is no evidence that MRI is harmful during pregnancy, but pregnant individuals should not take part as a precaution. Rarely, tattoos may become warm during MRI scanning. Participants will be advised to inform the MRI operator immediately if they experience any discomfort during the scan.

Where is the study run from?
The study will be run at approximately five NHS secondary care hospitals in the UK. Participants will be recruited through dermatology and rheumatology departments caring for adults with psoriasis or psoriatic arthritis.

When is the study starting and how long is it expected to run for?
The study is expected to begin in June 2026. Recruitment is anticipated to take place over approximately 12 months. Each participant will take part in the study for approximately 8 months. This duration includes the time between enrolment and starting Bimekizumab treatment, as treatment initiation may be delayed as part of routine NHS care pathways.

Who is funding the study?
The trial is funded by UCB Biopharma SRL (Belgium)

Who is the main contact?
Mimi Bogale
Trial Manager
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Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
None - BALANCE Trial Manager

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Additional identifiers

Integrated Research Application System (IRAS)
340351

Central Portfolio Management System (CPMS)
60927

UCB Biopharma SRL Grant Codes
600472

Study information

Scientific Title
A pilot mechanistic study to investigate the impact of Bimekizumab on liver inflammation in psoriatic disease

Acronym
BALANCE

Study objectives
Primary objectives:
1. To understand how the medication Bimekizumab, which blocks two inflammation-causing proteins (IL-17A&F), affects liver inflammation and fibrosis (thickening and scarring) in patients with psoriatic disease

Secondary objectives:
1. To understand how the medication Bimekizumab, which blocks two inflammation-causing proteins (IL17A&F), affects inflammation and fibrosis (thickening and scarring) in the heart, lungs, kidneys, pancreas, and spleen in patients with psoriatic disease
2. To explore whether organ inflammation and fibrosis (thickening and scarring) is similar in

patients with psoriasis and psoriatic arthritis
3. To explore if liver disease is associated with disease activity in patients with psoriasis and psoriatic arthritis
4. To explore if inflammation and fibrosis (thickening and scarring) of the heart, lungs, kidneys, pancreas and spleen is associated with disease activity in patients with psoriasis and psoriatic arthritis
5. To explore how treatment with Bimekizumab affects symptoms and quality of life in people with psoriatic disease, based on what patients report themselves

Exploratory objectives:
1. To explore the cellular drivers (which types of cells) and soluble mediators (chemical signals) of inflammation in patients with psoriatic disease
2. To explore how the genes of the microbes living in the body may contribute to inflammation in people with psoriatic disease

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 15/07/2026, East of England - Cambridge Central REC (Equinox House City Link, Nottingham, NG2 4LA, United Kingdom; no telephone number provided; cambridgecentral.rec@hra.nhs.uk), ref: 26/EE/0092

Primary study design
Observational

Secondary study design
Cohort study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Inflammatory and immune system, Musculoskeletal

Interventions
Participants with psoriatic disease who are planned to commence Bimekizumab treatment (a dual IL-17A&F inhibitor) as part of routine NHS standard of care will be recruited and followed prospectively.

The study involves up to four visits: Screening (Visit 1), Pre-treatment MRI (Visit 2), 24-week follow up (Visit 3) and 24-week post-treatment MRI scan (Visit 4).
The aim is to monitor participants before and after starting Bimekizumab.

Screening (Visit 1)
This clinic visit checks whether a person is suitable to take part in the study and can align with the participant's routine care clinic appointment.
Participants learn about the study, provide informed consent, and undergo checks to confirm eligibility. Health information is collected, and blood samples are taken for assessment.
Participants will be provided with a stool sample collection kit and diet questionnaire to complete at home and return in pre-paid packaging to the central laboratory.

Study Registration (no visit required)
After Visit 1, the clinical team reviews standard of care blood tests from Visit 1. These results are used to confirm whether the person can safely begin Bimekizumab. If these results were available (from previous test results within the last month) and reviewed during Visit 1, registration can occur at Visit 1.

Pre-treatment MRI (Visit 2)
Participants undergo an MRI scan before starting Bimekizumab treatment. If suitable routine blood test results were available at Visit 1, this scan may take place on the same day as Visit 1 to reduce the number of visits required.

Baseline (Day 0 the start date of Bimekizumab therapy)
Participants begin Bimekizumab treatment. No clinic visit is needed for this. The medication start date will be recorded in the clinical database.

24-week follow up (Visit 3)
24 weeks after Bimekizumab treatment begins, participants return to the clinic. The same health assessments and participant- completed questionnaires performed at Screening are repeated, and blood samples are taken to measure changes since starting Bimekizumab. Similar to visit 1, participants will be provided a stool sample collection kit and diet questionnaire, to complete at home and return in pre-paid packaging to the central laboratory.

24-week post-treatment MRI scan (Visit 4)
Participants undergo a follow-up MRI scan around the same time as Visit 3. When possible, this scan can be scheduled for the same day as Visit 3 to minimise the burden to participants.

Intervention Type
Other

Primary outcome(s)
1. Liver cT1 level and Liver proton density fat fraction (PDFF) measured using MRI scans obtained using the CoverScan™ at pre-treatment and 24 weeks post-treatment

Key secondary outcome(s)
1. MRI biomarkers of fibro-inflammation in heart, lungs, kidneys, pancreas and spleen measured using MRI scans obtained using the CoverScan™ at pre-treatment and 24 weeks post-treatment

2. Disease activity measures measured using clinical data and patient-reported questionnaire at pre-treatment and 24-weeks post-treatment

3. Symptoms and quality of life measured using SF-36, DLQI (PsO only), HAQ (PsA only), BASDAI (PsA and axial disease only), PsAID (PsA only), spinal Pain VAS (PsA and axial disease only) at pre-treatment and 24-week post treatment

4. Effects on the immune system, inflammation, gut bacteria and diet measured using blood and stool samples will be used to study different types of immune cells, inflammatory markers and genetic material from gut bacteria. Participants will also complete a questionnaire about their diet at pre-treatment and 24-week post treatment

Completion date
31/10/2028

Eligibility

Key inclusion criteria
1. Aged 18 years or over
2. Confirmed diagnosis of Psoriasis or Psoriatic Arthritis, and are eligible and due to start systemic treatment with Bimekizumab as part of routine NHS care
3. Willing and able to give informed consent

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
110 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Any contraindication to magnetic resonance imaging (MRI) (including pregnancy, extensive tattoos, pacemaker, shrapnel injury, severe claustrophobia) or any other disorder which may put the participant at risk
2. Previous IL-17 inhibitor therapy for any indication
3. Regular alcohol intake of >28 units/week and/or a history of binge drinking
4. Patients with known or suspected autoimmune hepatitis, viral hepatitis or Wilson's disease
5. Participating or planning to participate in another interventional clinical study/trial during the study period that, in the opinion of the investigator, could affect BALANCE outcomes
6. Any other cause, including a significant disease or disorder which, in the opinion of the investigator, may either put the participant at risk because of participation in the trial, or may influence the participant's ability to participate in the trial

Date of first enrolment
15/06/2026

Date of final enrolment
30/04/2027

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Leeds Teaching Hospitals NHS Trust
St. James's University Hospital
Beckett Street
Leeds
England
LS9 7TF

Study participating centre
Manchester University NHS Foundation Trust
Cobbett House
Oxford Road
Manchester
England
M13 9WL

Study participating centre
University Hospitals Birmingham NHS Foundation Trust
Queen Elizabeth Hospital
Mindelsohn Way
Edgbaston
Birmingham
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B15 2GW

Study participating centre
Nuffield Orthopaedic Centre
Windmill Road
Headington
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OX3 7HE

Sponsor information

Organisation
University of Oxford

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Industry

Funder Name
UCB Biopharma SRL

Results and Publications

Individual participant data (IPD) sharing plan

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1.0	16/03/2026	01/06/2026	No	Yes
Protocol file	version 1.0	16/03/2026	01/06/2026	No	No