ISRCTN17691638 https://doi.org/10.1186/ISRCTN17691638

Trial of stopping or continuing biologics ahead of orthopaedic surgery

Submission date
27/04/2023

Recruitment status
No longer recruiting

Registration date
03/05/2023

Overall study status
Ongoing

Last Edited
25/03/2026

Condition category
Musculoskeletal Diseases

[X] 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
Rheumatoid arthritis, psoriatic arthritis and ankylosing spondylitis are common forms of inflammatory arthritis. They are caused by an overactive immune system and are treated with medicines that reduce pain and inflammation. In recent years, special immune-suppressing medicines, called biologics, have been developed, which are very effective in controlling the arthritis disease process and symptoms but can increase the risk of some infections. People with inflammatory arthritis often need orthopaedic surgery (e.g. joint replacement) to relieve pain and improve function due to the damage caused by arthritis. The potential for increased risk for surgical site infections is a particular concern for patients undergoing orthopaedic surgery as these can be associated with long-term pain and the need for further surgery. Currently, biologics are usually stopped before any planned operation to try and reduce the risk of infection and other complications such as slow wound healing. However, stopping biologics increases the risk of painful and debilitating flares and delays recovery from surgery. Flares are often treated with steroids, which can increase the infection risk and delay wound healing. There are no randomised trials to support the current guidance on stopping biologics before surgery.

Who can participate?
Patients over the age of 18 who have inflammatory arthritis, are taking biologic medications, and are due to have orthopaedic surgery.

What does the study involve?
Participants will either be asked to stop taking their biologic medication or continue taking it ahead of their surgery; this will be decided at random by a computer.
Both groups of participants will then be followed up for 1 year after their surgery to see whether there was a difference in their quality of life, arthritis disease activity, infections, hospital admissions, and the cost of these treatments. Participants recruited after February 2026 will be followed to the 12week primary time point as a minimum.

What are the possible benefits and risks of participating?
The results of this study will help us find out how best to treat patients with inflammatory arthritis who need orthopaedic surgery in the future. As with any treatment, there are possible risks and benefits. The risk for these treatments includes the potential for a flare of arthritis and

the potential for an infection after surgery. Participating in this study will not harm or disadvantage participant's care and participants will be monitored regularly as part of usual NHS care.

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

When is the study starting and how long is it expected to run for?
September 2022 to August 2027

Who is funding the study?
National Institute for Health and Social Care Research (NIHR) (UK)

Who is the main contact?
Samantha Brady, samantha.gascoyne@york.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Samantha Brady

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Additional identifiers

Integrated Research Application System (IRAS)
321501

Central Portfolio Management System (CPMS)
55648

Study information

Scientific Title
PERI-operative biologic DMARD management: Stoppage or COntinuation during orthoPaEdic operations: The PERISCOPE trial

Acronym
PERISCOPE

Study objectives
What are the benefits and harms of continuation versus stoppage of biologics in patients with inflammatory arthritis undergoing orthopaedic surgery?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 24/04/2023, West of Scotland REC 3, (West of Scotland Research Ethics Service, Ground Floor Ward 11, Dykebar Hospital, Grahamston Road, Paisley, PA2 7DE, UK; +44 (0)141 314 0212; WoSREC3@ggc.scot.nhs.uk), ref: 23/WS/0049

Primary study design
Interventional

Study design
Multicentre superiority randomized controlled trial parallel-group and an internal pilot economic evaluation and nested qualitative study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Rheumatoid arthritis, psoriatic arthritis and ankylosing spondylitis, forms of inflammatory arthritis

Interventions
Current interventions as of 25/03/2026:
Stoppage of biologic: Participants will stop their biologic ahead of surgery in line with the British Society of Rheumatology guidelines
Continuation of biologic: Participants will continue their biologic as normal ahead of surgery and throughout the peri-operative period.

PERISCOPE is a multi-centre, 296-patient, superiority randomised controlled trial with parallel groups, with an internal pilot, economic evaluation and nested qualitative study.
Blinding: Blinding is not possible given the nature of the intervention.
Intervention arm:
Continuation of the named bDMARDs throughout the peri-operative period as prescribed prior to surgery. All other aspects of care will continue as per usual practice, including concomitant non-bDMARDs and post-surgical rehabilitation.
Usual care arm:
Stoppage of bDMARDs prior to surgery and recommencing treatment after wound healing and removal of sutures/clips, according to BSR recommendations. Given the pragmatic nature of the PERISCOPE trial, for any instances where a participant's surgery may be delayed (for medical or non-medical reasons), it will be at the clinician's discretion as to whether a participant needs to recommence bDMARDS whilst the surgery is rescheduled as per current clinical practice.
Data collection:

Following baseline assessments and randomisation, participants will be scheduled for their orthopaedic surgery and will complete follow-up assessments at 2, 4, 6, 9, 12, 26, and 52 weeks post-surgery. Participants recruited after February 2026 will be followed to the 12week primary time point as a minimum. All outcome measures collected from patients are validated measures. The visits and the data collected are summarised below:
Screening: Confirmation of the participant's eligibility, including the type of inflammatory arthritis and biologic. This is collected by investigator CRF and review of patient medical history. This is a face-to-face visit in the clinic.
Baseline: Participant demographics, disease history, primary outcome data, secondary outcome data - note that outcomes relating to surgery (e.g. wound healing and surgical satisfaction), and adverse events are not collected at this time point. This is collected by a participant questionnaire, investigator CRF and review of patient medical history.
This is a face-to-face visit in the clinic.
2,6,12,52 Week Follow-ups: All Primary and secondary outcome measures. For participants recruited after February 2026, a variable follow-up schedule will apply, with a 12-week time point collected as a minimum. This is collected by a participant questionnaire, investigator CRF and review of patient medical history. These are face-to-face visits in the clinic that are research-specific visits, however, they may coincide with routine surgical follow-ups, where not possible face-to-face these will be completed remotely.
4,9 Week Follow-ups: The primary outcome measure is the only outcome collected at this timepoint and is collected by participant questionnaire. This is a remote visit (post/email)
26 Week follow-up: This is collected by a participant questionnaire. The primary and secondary outcomes are collected at this time point - note that as this data is collected remotely, outcomes collected by investigators (disease-specific measures, adverse events, disease activity (Physcian), and wound healing are not collected at this time point.
This is a remote visit (post/email)
The disease-specific outcomes involve both patient questionnaires and clinician physical examinations and are completed at the baseline, 2-, 6-, 12-, and 52-week timepoints, these are collected as part of standard care. 12-week data will be collected as a minimum for participants recruited after February 2026.
Internal Pilot and recruitment rate:
An internal pilot phase in a small number of centres will run during the first 9 months of the main trial, which will assess the assumptions about recruitment and provide guidance on optimising the trial processes.
The recruitment projection is based on 20 centres recruiting 1-2 patients per month for 32 months. The total sample size is 296 participants.
Patient identification:
Patients will be screened for the study who are; aged 18 or over; who have a diagnosis of RA, PsA, AS (including the juvenile onset of all three), who are currently prescribed the following bDMARDs: TNF inhibitors (e.g. adalimumab /etanercept/ golimumab/certolizumab pegol /infliximab); CTLA4-Ig (e.g abatacept); IL-6 inhibitors (e.g tocilizumab/sarilumab); IL-12/23 inhibitors (e.g ustekinumab); IL-17 inhibitors (e.g secukinumab/ixekizumab); IL-23 p19 inhibitor (e. g guselkumab/risankizumab); and are scheduled to undergo elective orthopaedic surgery. Potentially eligible participants will be identified by screening the waiting lists for orthopaedic surgery across the participating sites. Many of these patients will be identified in the combined rheumatology-orthopaedic Multidisciplinary team clinics (MDT clinics). In addition, patients with inflammatory arthritis and on bDMARDs presenting to secondary care with an orthopaedic problem needing a surgical intervention will be screened for eligibility by the local team and approached to establish if they are potentially interested in participating in the study.
Only patients who are willing and able to give informed consent for participation in the study will be enrolled and they may request to leave the study at any time and without needing to provide the research team with a reason.

Pragmatic design: The trial is designed to be pragmatic and not to be a burden to patients; we intend to align follow-up assessments with regular hospital visits, which are common in patients who have undergone elective orthopaedic surgery. There will be three patient questionnaires at 4 (PROMIS-29 only), 9 (PROMIS-29 only), and 26 weeks, which do not align with hospital visits. These questionnaires will either be emailed to the participant, collected over the telephone with a researcher, or posted out for completion (a free post envelope will be included for return).
Qualitative study: The PERISCOPE trial will integrate a qualitative study in parallel to the internal pilot and full trial. This will focus on the patients' and clinicians' acceptability and experience of continuation/stoppage of bDMARDs in the perioperative period, and the impact post-operatively. Participation will be optional for patients (included on main study consent form). Health care staff will be provided with a PIS and consent form. Interviews are likely to be a mixture of face-to-face, video (via Zoom) or telephone call. If interviews are conducted face to face this will be in a location convenient to the participant (i.e. their home, NHS premises).
Healthcare staff: Semi-structured interviews with approximately 10 orthopaedic surgeons and 10 rheumatologists. The interviews will last around 30 to 40 minutes.
Patients: Semi-structured interviews with 30 patients (25 trial participants and 5 patients who declined to participate in the trial). The purpose is to explore the acceptability and experience of continuing/stopping bDMARDs in the pre-operative period and how the potential trade-off between risks of infection versus disease flare is perceived by patients. The interview is likely to last between 30–60 minutes.
Declining site leads: A purposive sample of up to 10 of declining site leads will be invited to take part in brief, semi-structured telephone interviews lasting around 15-20 minutes. The interview questions will further explore the reasons why their site declined to take part in the trial.
PPI perspective: In preparation for the PERISCOPE trial a number of patient advisory group (PAG) meetings have been conducted in Leeds and Oxford. The patient engagement work has included 17 people with IA (RA, PsA, AS and JIA: all represented) who are taking bDMARDs and have had orthopaedic surgery. The study protocol presented here was co-produced with the PAG, including inclusion and exclusion criteria, study schedule and primary and secondary outcome measures, including outcome assessment tools, as well as ways to support diversity and inclusivity in PERISCOPE.

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Intervention Type
Biological/Vaccine

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
bDMARDs and biosimilars of: TNF inhibitors (e.g. adalimumab /etanercept/ golimumab /certolizumab pegol/infliximab); CTLA4-Ig (e.g. abatacept); IL-6 inhibitors (e.g. tocilizumab /sarilumab); IL-12/23 inhibitors (e.g. ustekinumab); IL-17 inhibitors (e.g. secukinumab /ixekizumab); IL-23 p19 inhibitors (e.g. guselkumab/risankizumab)

Primary outcome(s)
Self-reported physical, mental, and social health measured using the Patient Reported Outcomes: Measurement Information System (PROMIS-29) questionnaire over the first 12 weeks (2, 4, 6, 9, and 12 weeks) post-surgery

Key secondary outcome(s)
Current secondary outcome measures as of 16/02/2024:

1. Self-reported physical, mental, and social health measured using the Patient Reported Outcomes: Measurement Information System (PROMIS-29) questionnaire at 26 and 52 weeks post-surgery
2. Level of disbility measured using the PROMIS Health Assessment Questionnaire Disability Index (HAQ) at 2, 6, 12, 26, and 52 weeks post-surgery

3. Health-related quality of life measured using EQ-5D-5L at 2, 6, 12, 26, and 52 weeks post-surgery
4. Disease activity measured using a generic global numeric rating scale (NRS) at 2, 6, 12, 26, and 52 weeks post-surgery
5. Medication use measured using patient medical records at 2, 6, 12, 26, and 52 weeks post-surgery
6. Healthcare resource use measured using patient medical records at 2, 6, 12, 26, and 52 weeks post-surgery
7. Disease activity measured using a generic global numeric rating scale as assessed by the treating physician at 2, 6, 12, and 52 weeks post-surgery
8. Surgical site infection, defined by the 1992 CDC criteria, measured using patient medical records at 2,6,12,52 weeks post-surgery
9. Delayed wound healing, defined as a surgical incision that has healed by primary intention without any evidence of gaping or dehiscence. Any wound that has not healed fully by primary intention by 2 weeks post-surgery, will be considered as “delayed wound healing” confirmed at 2, 6, 12, 52 weeks post surgery
10. Disease-Specific outcomes are measured using the following methods at 2, 6, 12, and 52 weeks post surgery:
10.1. Clinical Disease Activity Index for Rheumatoid Arthritis (CDAI)
10.2. Bath Ankylosing Spondylitis Disease Activity Index (BASDAI)
10.3. Bath Ankylosing Spondylitis Functional Index (BASFI)
10.4. Assessment of Spondyloarthritis International Society Health Index (ASAS-HI)
10.5. 66/68 Joint count
10.6. Leeds Enthesitis Index (LEI)
10.7. Body surface area (BSA) for skin
10.8. Dactylitis Severity Score (DSS)
10.9. Numerical rating scale (NRS)

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Previous secondary outcome measures:

1. Disease-specific outcomes measured using the PROMIS-29 questionnaire at 26 and 52 weeks post-surgery
2. Level of disbility measured using the PROMIS Health Assessment Questionnaire Disability Index (HAQ) at 2, 6, 12, 26, and 52 weeks post-surgery
3. Health-related quality of life measured using EQ-5D-5L at 2, 6, 12, 26, and 52 weeks post-surgery
4. Disease activity measured using a generic global numeric rating scale (NRS) at 2, 6, 12, 26, and 52 weeks post-surgery
5. Medication use measured using patient medical records at 2, 6, 12, 26, and 52 weeks post-surgery
6. Healthcare resource use measured using patient medical records at 2, 6, 12, 26, and 52 weeks post-surgery
7. Disease activity measured using a generic global numeric rating scale as assessed by the treating physician at 2, 6, 12, and 52 weeks post-surgery
8. Surgical site infection, defined by the 1992 CDC criteria, measured using patient medical records at 2,6,12,52 weeks post-surgery
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10.7. Body surface area (BSA) for skin
10.8. Dactylitis Severity Score (DSS)
10.9. Numerical rating scale (NRS)

Completion date
31/08/2027

Eligibility

Key inclusion criteria
Current inclusion criteria as of 11/10/2024:

1. Adults aged 18 years and over with RA, PsA, or AS (including juvenile onset of all three)
2. Currently prescribed one of the following bDMARDs: TNF inhibitors (e.g. adalimumab /etanercept/ golimumab/certolizumab pegol/infliximab); CTLA4-Ig (e.g. abatacept); IL-6 inhibitors (e.g. tocilizumab/sarilumab); IL-12/23 inhibitors (e.g. ustekinumab); IL-17 inhibitors (e. g. secukinumab/ixekizumab); IL-23 p19 inhibitors (e.g. guselkumab/risankizumab).
3. Deemed by the clinical care team to be fit for surgery and have no contraindications to continued bDMARD use
4. Scheduled to undergo elective orthopaedic surgery (Soft tissue, metalwork, or Joint replacement)
5. Able to consent and complete follow-up

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Previous inclusion criteria:

1. Consenting adults aged 18 and over with RA, PsA, AS (including the juvenile onset of all three)
2. Currently prescribed the following bDMARDs: TNF inhibitors (adalimumab /etanercept/ golimumab/certolizumab pegol/infliximab); CTLA4-Ig (abatacept); IL-6 inhibitors (tocilizumab /sarilumab); IL-12/23 inhibitors (ustekinumab); IL-17 inhibitors (secukinumab/ixekizumab); IL-23 p19 inhibitor (guselkumab/risankizumab).
3. Scheduled to undergo elective orthopaedic surgery
4. Deemed by the clinical care team to be fit for surgery and have no contraindications to continued biologic use
5. Able to consent and complete follow-up

Participant type(s)
Patient

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
Current exclusion criteria as of 13/08/2025:

1. Currently prescribed JAK inhibitors
2. Currently being treated with rituximab
3. Current use of systemic steroids (< 3 months of surgery date) other than those on a stable dose of <= 15mg per day
4. Previous history of native/prosthetic joint infection
5. Undergoing revision surgery
6. Patients who are pregnant

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Previous exclusion criteria:

1. Currently prescribed JAK inhibitors
2. Currently being treated with rituximab
3. Current use of systemic steroids (< 3 months) other than those on a stable dose of < = 5mg per day
4. Previous history of native/prosthetic joint infection
5. Undergoing revision surgery
6. Patients who are pregnant

Date of first enrolment
05/05/2023

Date of final enrolment
30/09/2026

Locations

Countries of recruitment
United Kingdom

England

Northern Ireland

Scotland

Wales

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

Study participating centre
Northern General Hospital
Herries Road
Sheffield
England
S5 7AU

Study participating centre
Queens Medical Centre
Derby Road
Nottingham
England
NG7 2UH

Study participating centre
John Radcliffe Hospital
Headley Way
Headington
Oxford
England
OX3 9DU

Study participating centre
Belfast City Hospital
51 Lisburn Rd
Belfast
Northern Ireland
BT9 7AB

Study participating centre
Gartnavel Royal Hospital
1055 Great Western Road
Glasgow
Scotland
G12 0XH

Study participating centre
NHS Lothian
Waverley Gate
2-4 Waterloo Place
Edinburgh
Scotland
EH1 3EG

Study participating centre
Southport and Ormskirk Hospital NHS Trust
Town Lane
Southport
England
PR8 6PN

Study participating centre
Lewisham and Greenwich NHS Trust
University Hospital Lewisham
Lewisham High Street
London
England
SE13 6LH

Study participating centre
Queen Elizabeth Hospital Kings Lynn
Gayton Road
Queen Elizabeth Hospital Site
King's Lynn
England
PE30 4ET

Study participating centre

NHS Ayrshire and Arran
PO Box 13, Boswell House
10 Arthur Street
Ayr
Scotland
KA7 1QJ

Study participating centre
The Royal Wolverhampton NHS Trust
New Cross Hospital
Wolverhampton Road
Heath Town
Wolverhampton
England
WV10 0QP

Study participating centre
Royal National Orthopaedic Hospital
Brockley Hill
Stanmore
England
HA7 4LP

Study participating centre
Northumbria Healthcare NHS Foundation Trust
North Tyneside General Hospital
Rake Lane
North Shields
England
NE29 8NH

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

Study participating centre

NHS Lanarkshire
14 Beckford Street
Hamilton
Scotland
ML3 0TA

Study participating centre
Royal Orthopaedic Hospital
The Woodlands
Bristol Road South
Northfield
Birmingham
England
B31 2AP

Study participating centre
Homerton University Hospital
Homerton Row
London
England
E9 6SR

Study participating centre
University Hospital Southampton NHS Foundation Trust
Southampton General Hospital
Tremona Road
Southampton
England
SO16 6YD

Sponsor information

Organisation
University of Leeds

ROR
https://ror.org/024mrxd33

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

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be available from catherine.hewitt@york.ac.uk upon reasonable request. The release of any data will be provided in an anonymised format and securely transferred to the requester. Data will only be released in accordance with participants' consent. External data requests will only be considered once the main results paper has been published and for as long as York Trials Unit retains the data. Data requests will be considered by the Trial Management Group who will notify the Sponsor.

To inform the decision on data release, the requester should provide a protocol of the planned work that includes what data are required, the planned analyses and where the data will be securely stored. Data will only be shared with projects that the group consider to be well-justified and valuable secondary research projects. An agreement stating the conditions of data release should be in place before any data are shared with the requester.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		25/06/2024	25/06/2024	Yes	No
HRA research summary			20/09/2023	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes