ISRCTN27974201 https://doi.org/10.1186/ISRCTN27974201

Hip surgical techniques to enhance rehabilitation

Submission date
08/08/2023

Recruitment status
No longer recruiting

Registration date
19/09/2023

Overall study status
Ongoing

Last Edited
03/06/2025

Condition category
Surgery

[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
Total hip replacement (THR) is a successful operation for the majority of people. However, more than 10% of patients remain with pain in the operated hip one year after their operation and more than 6% are dissatisfied with their surgery.
The study will assess whether methods for completing total hip replacements that reduce soft tissue damage during surgery improve patient outcomes. In order to reach the hip joint during total hip replacement surgery, surgeons cut through tendons, which attach muscles to bone and provide stability and strength during daily activities. The study will investigate three different ways that the hip joint can be accessed for a total hip replacement. The Posterior Approach (PA) is the most frequently used method, and it involves cutting three tendons at the back of the hip joint, which are then repaired once the artificial hip is in place. It allows a clear view of the hip joint so the artificial ball and socket can be correctly positioned. The Piriformis Sparing Posterior Approach (PSPA) is a modified version of the PA, which cuts two tendons. The Spare Piriformis And Internus, Repair Externus (SPAIRE) approach is also a modification of the PA, where one tendon is cut. The PSPA and SPAIRE approaches that cut fewer tendons aim to reduce recovery time, improve rehabilitation, and improve patient satisfaction. However, cutting fewer tendons can limit the visibility and access to the hip joint, which can make positioning the socket of the artificial hip more challenging. Robotic guided surgery allows surgeons to position the artificial hip components very accurately; this may also help with the reduced visibility of the joint when fewer tendons are cut. By using robotic-guided surgery for all approaches, we will be able to assess whether cutting fewer tendons during surgery improves patient outcomes.

Who can participate?
Patients aged 18 years or older, with osteoarthritis of the hip

What does the study involve?
Participants will be randomised to one of three groups (1:1:1). Group 1 of the trial (control group) will receive THR with the current gold standard PA, in which three tendons are released. Group 2 will receive THR with a PSPA, in which two tendons are released. Group 3 will receive THR with a SPAIRE approach in which one tendon is released. All participants will receive THR using MAKO robotic guidance.

What are the possible benefits and risks of participating?
Participating in the HIPSTER trial will ensure patients are at the cutting edge of hip research and will ensure they are able to have the MAKO robot being used in their procedure to help plan their procedure and also help optimise implant positioning. They will be guiding national and worldwide education on tendon sparing approaches for hip replacement surgery and making a difference to help guide surgeons choose the right surgical approach for a patient's total hip replacement. This will subsequently ensure surgeons choose the best performing approach for their patients with subsequent benefit in patient outcomes.
Risks of participating are minimal and not increased compared to the usual risk of hip replacement surgery. There is some added (mostly virtual) contact required to complete patient reported outcome measures and the need to wear an activity monitor watch prior to and after surgery, and subsequent return of these monitors to the research team. One extra blood test is required after surgery where only a small amount of blood is required. No other risks are anticipated.

Where is the study run from?
Royal Devon University Healthcare NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
January 2023 to December 2026

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

Who is the main contact?
Holly Whitmore
hipster@exeter.ac.uk

Contact information

Type(s)
Scientific

Contact name
Mrs Holly Whitmore

Contact details
Royal Devon University Healthcare NHS Foundation Trust
Princess Elizabeth Orthopaedic Centre
Royal Devon and Exeter Hospital (Wonford)
Barrack Road
Exeter
United Kingdom
EX2 5DW
+44 (0)1392 403473
holly.whitmore@nhs.net

Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)
327702

Protocol serial number
CPMS 57474, NIHR150537, IRAS 327702

Study information

Scientific Title
HIP Surgical Techniques to Enhance Rehabilitation - a randomised controlled trial

Acronym
HIPSTER

Study objectives
Tendon sparing approaches to Total Hip Replacements such as the Piriformis-Sparing Posterior Approach (PSPA) and the Spare Piriformis And Internus Repair Externus approach (SPAIRE), help provide improved outcomes compared to patients undergoing the current standard Posterior Approach (PA).

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 19/09/2023, Seasonal REC (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 207 104 8328; Rebecca.throup@hra.nhs.uk), ref: 23/LO/0624

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Hip surgery

Interventions
Current interventions as of 10/09/2024:

This is a single-centre, double-blind, parallel three-arm, randomised-controlled, superiority trial of patients undergoing Total hip replacement surgery. The trial is designed to compare each of two tendon-sparing versions of the Posterior approach (PA) for THR (PSPA and SPAIRE) with the standard PA. A range of outcome measures will be used including Patient Reported Outcome Measures (PROMs), physical activity monitoring, clinical blood biomarkers and clinical outcomes. Participants will be randomised to one of three groups (1:1:1). Group 1 of the trial (control

group) will receive THR with the current gold standard PA, in which three tendons are released. Group 2 will receive THR with a PSPA, in which two tendons are released. Group 3 will receive THR with a SPAIRE approach in which one tendon is released. All participants will receive THR using MAKO robotic guidance. This will allow consistent positioning of the hip replacement components across all trial groups, allowing the effect of reducing the number of tendons released to be more reliably investigated. All other care will be the same for all participants. All participants will receive routine anaesthetic, as per standard care provided during THR procedures and standard post-operative physiotherapy.

The SPAIRE approach has been developed recently by Professor Timperley in the Exeter Hip unit and its use has been increasing. This project plans to assess its outcomes and compare it to the PSPA approach which is routinely performed in the Exeter Hip unit over the last 20 years. The control arm (PA) has been chosen as this is the routine practice of the majority of surgeons in the UK to allow generalisability of results and also to help improve the impact of any study findings on the general Orthopaedic population nationally.

Participants in the study will have the following additions to their routine THR care:
Pre-operatively: Eligibility check with PIS provided to patient. Patient contacted by Research Team for verbal agreement of study participation.

6-8 weeks prior to surgery (in clinic): Patient consented to study in routine THR consent clinic (so no additional hospital visits required). At this appointment blood biomarkers via a blood test will be collected, an activity monitor issued, PROMs (OHS, LEFS, EQ-5D-5L) completed.

Day 0/1 (either at Nightingale hospital Exeter or in Princess Elizabeth Orthopaedic Centre at RDUH): Blood biomarkers collected.

6 weeks post-operative (alongside routine 6 week post-operative review in clinic): Blood biomarkers collected, activity monitor issued, PROMs (OARS, OACS, OHS, LEFS, EQ-5D-5L, SAPS) completed.

6 months (24 weeks) post-operative (remotely): Activity monitor issued, PROMS (OHS, LEFS, EQ-5D-5L, SAPS) collected, and the documenting of any additional surgical procedures since 6 weeks post-op.

12 months (52 weeks) post-operative (remotely): Activity monitor issued, PROMS (OHS, LEFS, EQ-5D-5L, SAPS) collected, and the documenting of any additional surgical procedures since 6 months post-op.

The project design, methodology and research outcomes have all been developed in conjunction with the Exeter Hip unit patient project design group along with involvement of patients on the Trial management group. They have especially recommended the use of the various PROMS and also the activity monitors.

———

Previous interventions:

This is a single-centre, double-blind, parallel three-arm, randomised-controlled, superiority trial of patients undergoing Total hip replacement surgery. The trial is designed to compare each of two tendon-sparing versions of the Posterior approach (PA) for THR (PSPA and SPAIRE) with the standard PA. A range of outcome measures will be used including Patient Reported Outcome

Measures (PROMs), physical activity monitoring, clinical blood biomarkers and clinical outcomes. Participants will be randomised to one of three groups (1:1:1). Group 1 of the trial (control group) will receive THR with the current gold standard PA, in which three tendons are released. Group 2 will receive THR with a PSPA, in which two tendons are released. Group 3 will receive THR with a SPAIRE approach in which one tendon is released. All participants will receive THR using MAKO robotic guidance. This will allow consistent positioning of the hip replacement components across all trial groups, allowing the effect of reducing the number of tendons released to be more reliably investigated. All other care will be the same for all participants. All participants will receive routine anaesthetic, as per standard care provided during THR procedures and standard post-operative physiotherapy.

The SPAIRE approach has been developed recently by Professor Timperley in the Exeter Hip unit and its use has been increasing. This project plans to assess its outcomes and compare it to the PSPA approach which is routinely performed in the Exeter Hip unit over the last 20 years. The control arm (PA) has been chosen as this is the routine practice of the majority of surgeons in the UK to allow generalisability of results and also to help improve the impact of any study findings on the general Orthopaedic population nationally.

Participants in the study will have the following additions to their routine THR care:
Pre-operatively: Eligibility check with PIS provided to patient. Patient contacted by Research Team for verbal agreement of study participation.

6-8 weeks prior to surgery (in clinic): Patient consented to study in routine THR consent clinic (so no additional hospital visits required). At this appointment blood biomarkers via a blood test will be collected, an activity monitor issued, PROMs (OHS, LEFS, EQ-5D-5L) completed.

Day 0/1 (either at Nightingale hospital Exeter or in Princess Elizabeth Orthopaedic Centre at RDUH): Blood biomarkers collected.

6 weeks post-operative (alongside routine 6 week post-operative review in clinic): Blood biomarkers collected, activity monitor issued, PROMs (OARS, OACS, OHS, LEFS, EQ-5D-5L, SAPS) completed.

6 months (24 weeks) post-operative (remotely): Activity monitor issued, PROMS (OHS, LEFS, EQ-5D-5L, SAPS) collected.

12 months (52 weeks) post-operative (remotely): Activity monitor issued, PROMS (OHS, LEFS, EQ-5D-5L, SAPS) collected.

The project design, methodology and research outcomes have all been developed in conjunction with the Exeter Hip unit patient project design group along with involvement of patients on the Trial management group. They have especially recommended the use of the various PROMS and also the activity monitors.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Pain, sleep, nausea and feeling unwell, and mobility, are measured using the Oxford Arthroplasty Early Recovery Score (OARS) at 6 weeks post-operatively.

Key secondary outcome(s))

1. Muscle damage and inflammation are measured using serum creatinine kinase (CK) and C-reactive protein (CRP) blood biomarkers at the pre-operative assessment, day 0/1, and at 6 weeks post-operatively.
2. Walking and sleep quality are measured using activity monitors to collect 2 weeks of continuous data at the pre-operative assessment, and 6 weeks, 6 months, and 12 months post-operatively.
3. Patient perspective on their treatment is measured using the Oxford Arthroplasty Early Change Score (OACS) at 6 weeks post-operatively.
4. Pain and function are measured using the Oxford Hip Score (OHS) at the pre-operative assessment, and 6 weeks, 6 months, and 12 months, post-operatively.
5. Function is measured using the Lower Extremity Functional Scale (LEFS) at the pre-operative assessment, and 6 weeks, 6 months, and 12 months post-operatively.
6. Mobility, self-care, usual activities, pain/discomfort, and anxiety/depression are measured using the EQ-5D-5L questionnaire at the pre-operative assessment, and 6 weeks, 6 months, and 12 months post-operatively.
7. Patient satisfaction is measured using the Self-Administered Patient Satisfaction Scale (SAPS) at 6 weeks, 6 months, and 12 months post-operatively.
8. Clinical outcomes: ‘duration of surgery’, ‘blood loss’, and ‘length of hospital stay’ are recorded during and immediately after surgery.
9. Additional analgesia use (not included as part of standard care) is recorded during the first 6 weeks post-operatively.
10. The safety of approaches is measured by recording adverse events from the day of surgery until 12 months post-operatively.

Completion date
31/12/2026

Eligibility

Key inclusion criteria
1. Patients with osteoarthritis of the hip
2. Patients suitable for a cementless acetabular component
3. Patients over the age of 18 years
4. Patients of any Body Mass Index (BMI)
5. Patients willing and able to provide informed consent in English

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Patients with active systemic or local infection that would preclude standard THR surgery
2. Patients undergoing bilateral THR in same operative episode
3. Patients unable to give informed consent
4. Patients unable or unwilling to take part in the trial process, including patients unable to undertake activity monitoring data collection or complete the PROMS questionnaires in English (English is the only common translation available in official translations of all six PROMS)

Date of first enrolment
31/10/2023

Date of final enrolment
14/08/2025

Locations

Countries of recruitment
United Kingdom

England

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
Royal Devon University Healthcare NHS Foundation Trust

Funder(s)

Funder type
Government

Funder Name
NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC)

Results and Publications

Individual participant data (IPD) sharing plan

At the end of the study the researchers will store anonymised research data and outputs in the University of Exeter's Open Research Exeter repository (https://ore.exeter.ac.uk/repository/) indefinitely. All trial data excluding personally identifiable information will be made available indefinitely. Consent from participants will be obtained for data to be stored for the purposes of other ethically approved research in the future and that data will be shared anonymously.

IPD sharing plan summary

Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 4.0	18/09/2023	24/10/2023	No	Yes