

# Hip surgical techniques to enhance rehabilitation

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<b>Registration date</b> 19/09/2023	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 03/06/2025	<b>Condition category</b> Surgery	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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

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## Contact information

### Type(s)

Scientific

### Contact name

Mrs Holly Whitmore

### Contact details

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## Additional identifiers

EudraCT/CTIS number

Nil known

**IRAS number**

327702

**ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

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

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet**

See study outputs table

## **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.

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#### Previous interventions:

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## **Intervention Type**

Procedure/Surgery

## **Primary outcome measure**

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

## **Secondary outcome measures**

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.

## **Overall study start date**

01/01/2023

## **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

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

Planned Sample Size: 339; UK Sample Size: 339

**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**

England

United Kingdom

**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

**Sponsor details**

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Exeter  
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United Kingdom  
EX2 5DW  
+44 1392 403041  
alison.kerridge@nhs.net

**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.rdehospital.nhs.uk/>

**Funder(s)****Funder type**

Government

**Funder Name**

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

**Results and Publications****Publication and dissemination plan**

The Research Team will disseminate the results of the trial through leading academic journals in their field and will engage with academic and clinical communities through academic conferences and specialist hip meetings. The results will be posted on the publicly available registry. We intend to publish results around 12 months after the final follow-up once full analysis has been performed.

**Intention to publish date**

31/12/2027

**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?
<a href="#">Participant information sheet</a>	version 4.0	18/09/2023	24/10/2023	No	Yes