# Operative or non-surgical treatment of Perthes' disease

Submission date	Recruitment status Recruiting	[X] Prospectively registered			
29/07/2024		[X] Protocol			
Registration date 02/08/2024	Overall study status Ongoing	Statistical analysis plan			
		Results			
<b>Last Edited</b> 18/06/2025	<b>Condition category</b> Musculoskeletal Diseases	] Individual participant data			
		[X] Record updated in last year			

#### Plain English summary of protocol

Background and study aims

Perthes' disease is a rare condition of the hip joint and one of the most disabling conditions affecting children. It has a profound impact on the life of the child, and that of their family. The hip is a 'ball and socket' joint. This can be thought of as a scoop of ice cream, with the ice cream (the 'ball') sitting in an ice cream scoop (the 'socket'). Perthes' disease is caused by a problem with the blood supply to the hip, which means the ball doesn't get enough oxygen and nutrients to grow. When this happens, the hip loses its strength and flattens - like the ice cream melting and becoming squashed. In Perthes' disease there is a temporary loss of blood supply, which means that after some months the nutrients return, and the ball again hardens. However, the bone remains whatever shape it was when it became squashed. This can lead to a ball that doesn't fit well into the socket, which can cause pain, limitation to usual activities and severe hip arthritis in childhood.

About half of the surgeons in the UK currently believe that surgery can be helpful in 'controlling' the way that the ball of the hip flattens, which could result in a better-shaped hip and better outcomes for children. Surgery involves breaking the bone to re-orientate the ball to ensure that it deforms in a controlled way into the socket (called 'containment' surgery). The other half of surgeons do not undertake surgery, instead focusing on a package of care (called 'non-surgical or active containment') that involves physiotherapy, activity restriction and pain relief. Physiotherapy aims to maintain movement of the hip and keep the soft ball moving within the socket, allowing it to continually smooth its shape – i.e. the 'ice cream rolling within the scoop'. These surgeons believe that surgical containment is no better than active containment with the benefit that active containment does not expose the child to the unnecessary risks associated with surgery. Given how disabling Perthes' disease is, and the differences in how it is treated, patients, families, and health professionals ranked the management of Perthes' disease in the top five most important research priorities in children's orthopaedic surgery. This study aims to find out whether containment surgery is better than active containment for helping patients with Perthes' disease to be able to take part in activities.

Who can participate?

Children aged 5 years to 12 years inclusive with newly diagnosed Perthes' disease

What does the study involve?

If you decide you would like your child to take part, a member of the team will ask you to complete:

- 1. A consent form. Children will also be asked to complete an assent form. This shows that they also give their permission.
- 2. A contact information form so we can contact you about your child's progress.
- 3. A questionnaire about how the condition affects your child, pain, activities and feelings. This should take about 15 minutes. We will then allocate your child fairly to one of the two treatment groups in the study and the doctors and nurses will then begin treatment.

If you are allocated to active containment you will have a face-to-face personalised physiotherapy session with a therapist trained in this research study. They will spend time with you, discussing goals for your child in their recovery and providing education and advice around how to manage your child's Perthes' Disease. This will include discussions about how Perthes' Disease progresses and what to expect in terms of timeframes. It will also involve education around how to manage pain that is common with Perthes' Disease, this will involve advice about pain relief but also about how to manage pain without medication. The therapist will identify appropriate exercises, giving you access to a website and a mobile app that help guide the recovery through exercises and trustworthy sources of information. To enable active containment throughout recovery, the expertise of specially trained physiotherapists within specialist centres will be available to support local physiotherapists.

With your permission, the health professional might audio record the face-to-face personalised physiotherapy session to share with the central study team. The recording will be used to make sure the information is delivered in the best way. This is normal in research, but it is ok to say if you prefer not to have the session recorded. Any recording will be deleted 12 months after the research team checks it.

If you are allocated to surgery, your child will be scheduled for an operation, usually within about 4 months of the appointment. The surgery involves your child going to sleep with a general anaesthetic. When your child is asleep, a cut will be made in the skin and either the thigh (femur) or the hip (pelvis) bone will be divided. This surgery will realign the ball and socket of the hip, such that they fit together in the best way possible. The bone is then fixed to ensure that the ball sits well within the socket. This will try to help the hip to squash down and then regrow in the round shape of the socket. Depending on the type of surgery, your child may spend around 6 weeks in a special cast called a 'spica' and may need to use a wheelchair. Your child will have access to a physiotherapist after the surgery, which will be provided by the local treating physiotherapy team. Often, as your child recovers, a second operation is needed to remove any implants used to hold the bones in position.

During the research study, you will be seen for routine clinical follow-up at your treating hospital and we will have brief contact with you by text message and/or email on eight further occasions (3, 6, 9, 12, 18, 24, 30 and 36 months after enrolment). We will ask questions about pain, activities, how your child feels, hospital attendance, school attendance and costs that you may have incurred in relation to this hip problem (i.e. days absent from work etc.). For all children, we collect routinely taken radiographs for analyses.

What are the possible benefits and risks of participating?

The study compares the two treatments commonly used in the NHS. Each of the treatments has potential advantages and disadvantages.

1. Active containment': The goals are to maximise movement of the hip allowing it to continually smooth its shape. The benefit is the activity encourages the hip ball to re-form in the round shape of the socket, without the need for surgery. This continues throughout the disease process, with families encouraged to engage with therapy at home with support from the physiotherapists. Despite this treatment, the hip may not grow into a normal shape, which could cause pain and arthritis in the future.

2. Containment surgery, is done by breaking and resetting the bones around the hip. Children may be put in a plaster cast for around 6 weeks. The benefit is that surgery directs the ball of the hip into the socket, encouraging the hip ball to re-form in the round shape of the socket. However, there are very small risks related to the anaesthetic, along with small risks of infection, wound problems, pain or stiffness, injury to nerves supplying the foot and problems related to the metal implants. Also, there is often a need for a second operation to remove any metal implants. Despite this treatment, the hip may not grow into a normal shape, which could cause pain and arthritis in the future.

There will be extra surveys and questionnaires to complete.

#### Where is the study run from?

Alder Hey Children's NHS Foundation Trust is the sponsor for the study and has overall responsibility for the management of it. This study will be overseen by Oxford Clinical Trials Research Unit (OCTRU) with the day-to-day running of the study being completed by Oxford Trauma and Emergency Care at the University of Oxford. The research team has a lot of experience in caring for children and young people with injuries and is active in health research. Parents and children have been involved in the development of this study and are involved in the management.

When is the study starting and how long is it expected to run for? October 2023 to May 2030

Who is funding the study?

National Institute for Health and Care Research (NIHR) Health Technology Assessment (HTA) Programme (reference NIHR152309) (UK)

Who is the main contact?

- 1. Prof. Daniel Perry, OPNon-STOP@ndorms.ox.ac.uk
- 2. Alder Hey Children's NHS Foundation Trust, +44 (0)151 252 5570 or research@alderhey.nhs.uk

# Contact information

#### Type(s)

Public, Scientific

#### Contact name

**Prof Daniel Perry** 

#### ORCID ID

https://orcid.org/0000-0001-8420-8252

#### Contact details

University of Liverpool Dept Child Health Alder Hey Children's NHS Foundation Trust Alder Hey Children's Hospital Eaton Road Liverpool United Kingdom L14 5AB +44 (0)151 282 4661 danperry@liverpool.ac.uk

# Additional identifiers

#### Clinical Trials Information System (CTIS)

Nil known

#### ClinicalTrials.gov (NCT)

Nil known

#### Protocol serial number

CPMS 53594, IRAS 318800, NIHR152309

# Study information

#### Scientific Title

Op Non-STOP Study (Operative or Non-Surgical Treatment of Perthes' disease). A multi-centre prospective randomised superiority trial of containment surgery compared to optimised non-surgical care for Perthes' disease of the hip in children

#### **Acronym**

**OP Non-STOP** 

#### Study objectives

Current study hypothesis as of 05/08/2024:

Containment surgery is not superior to optimised non-surgical containment, amongst children treated for Perthes' disease in terms of lower extremity function.

### Previous study hypothesis:

Children treated with containment surgery for Perthes' disease have better lower extremity function than children treated with optimised non-surgical containment.

#### Ethics approval required

Old ethics approval format

# Ethics approval(s)

Approved 30/08/2024, West Midlands - Black Country Research Ethics Committee (Health Research Authority, 2 Redman Place, Stratford, E20 1JQ, UK; +44 (0)207 104 8010; blackcountry. rec@hra.nhs.uk), ref: 24/WM/0157

# Study design

Randomized; Interventional; Design type: Treatment, Surgery

# Primary study design

Interventional

#### Study type(s)

Treatment

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

Perthes' disease

#### **Interventions**

The proposed project is a two-phase trial.

Phase 1 (internal pilot) will take place at a minimum of 15 centres over a 12-month period and will confirm the expected rate of recruitment and data collection procedures.

Phase 2 is the expansion of the pilot into the full definitive trial. A full trial report for the funder and peer-reviewed publications of the main results will be generated after the completion of this phase.

All children aged 5-12 years inclusive presenting to the recruitment centres with Perthes' disease of the hip are potentially eligible to take part.

Upon presentation, children's eligibility for the study will be assessed, if eligible, informed consent/assent will be sought. Following this baseline questionnaires will be completed.

The children will then be split into two groups, using a research process called 'randomisation' to fairly allocate treatments:

- 1. Containment surgery (intervention): children will have an operation under a general anaesthetic. Whilst asleep, children randomised to active containment surgery will receive an operation on their hip.
- 2. Active (non-surgical) containment (comparator): children and families will receive an individual face-to-face best practice therapy session of up to 90 minutes with a trial-trained physiotherapist at the recruiting hospital/regional specialist centre.

After treatment, the parents and/or participants will be asked to complete further questionnaires at 3, 6, 9, 12, 18, 24, 30 and 36 months after randomisation. Data will be collected primarily electronically with email and/or text message prompts. No additional visits or procedures are required as part of the study protocol at any follow-up time point. We will also invite patients to consent to data sharing with the Non-Arthroplasty Hip Registry, which will enable the long-term results of the treatments under investigation. A full trial report for the funder and peer-reviewed publications of the main results will be generated after the completion of phase 2.

#### Intervention Type

Procedure/Surgery

### Primary outcome(s)

Function is measured using the PROMIS Proxy Mobility Score at 36 months post-randomisation

#### Key secondary outcome(s))

- 1. Function is measured using the PROMIS Proxy Mobility Score at Baseline, 3, 6, 9, 12, 18, 24, 30 and 36 months post-randomisation
- 2. Pain is measured using the Wong-Baker FACES pain rating scale at Baseline, 3, 6, 12, 18, 24, 30 and 36months post-randomisation
- 3. Quality of life is measured using the CHU-9D questionnaire at 3, 6, 9, 12, 18, 24, 30 and 36 months post-randomisation
- 4. Impact on family life is measured using the PROMIS Proxy Family Relationships Score at 3, 6, 9, 12, 18, 24, 30 and 36 months post-randomisation
- 5. Educational Participation is measured using a bespoke 'days of missed educational attendance' questionnaire at 3, 6, 9, 12, 18, 24, 30 and 36 months post-randomisation

- 6. Complication rate measured using a bespoke complications questionnaire at 6, 12, 18, and 36 months post-randomisation
- 7. Cost-effectiveness from the UK NHS and Personal Social Services perspective is measured using Healthcare and Personal Resource use, absence from work, purchased childcare and CHU-9D questionnaires at baseline (CHU-9D only), 6, 9, 12, 18, 24, 30 and 36 months post-randomisation
- 8. The degree of residual deformity is measured from routinely collected images of the hip or pelvis at 30-36 months post-randomisation

#### Completion date

31/05/2030

# Eligibility

#### Key inclusion criteria

- 1. Radiographic evidence of Perthes' disease
- 2. Radiographs demonstrate that the disease is in the initial, sclerotic or fragmentation stage
- 3. Aged 5 to 12 years inclusive
- 4. Willing and able to give informed assent/consent

#### Participant type(s)

Patient

#### Healthy volunteers allowed

No

#### Age group

Child

### Lower age limit

5 years

#### Upper age limit

12 years

#### Sex

All

#### Key exclusion criteria

- 1. There is evidence that the patient and/or parent would be unable to adhere to the study procedures or complete follow-up, such as insufficient comprehension
- 2. Child has undergone prior containment surgery on the affected hip (i.e. the hip to be randomised)
- 3. The child has previously been enrolled into the OP Non-STOP Study

#### Date of first enrolment

15/11/2024

#### Date of final enrolment

08/03/2027

# Locations

#### Countries of recruitment

United Kingdom

England

Scotland

Wales

# Study participating centre Alder Hey Children's Hospital

Eaton Road West Derby Liverpool United Kingdom L12 2AP

# Study participating centre The James Cook University Hospital

Marton Road Middlesbrough United Kingdom TS4 3BW

### Study participating centre Leeds Children's Hospital

Beckett Street Leeds United Kingdom LS9 7TF

# Study participating centre Musgrove Park Hospital (taunton)

Musgrove Park Hospital Taunton United Kingdom TA1 5DA

#### John Radcliffe Hospital

Headley Way Headington Oxford United Kingdom OX3 9DU

### Study participating centre Peterborough City Hospital

Edith Cavell Campus Bretton Gate Bretton Peterborough United Kingdom PE3 9GZ

#### Study participating centre Royal Aberdeen Children's Hospital

Westburn Drive Aberdeen United Kingdom AB25 2ZG

#### Study participating centre Royal Berkshire Hospital

Royal Berkshire Hospital London Road Reading United Kingdom RG1 5AN

### Study participating centre Royal Alexandra Children's Hospital

Eastern Road Brighton United Kingdom BN2 5BE

#### Study participating centre Royal National Orthopaedic Hospital Brockley Hill

Stanmore United Kingdom HA7 4LP

# Study participating centre The Royal Victoria Infirmary

Newcastle upon Tyne United Kingdom NE1 4LP

### Study participating centre Sheffield Childrens Hospital

Western Bank Sheffield United Kingdom S10 2TH

# Study participating centre University Hospital (coventry)

Clifford Bridge Road Coventry United Kingdom CV2 2DX

# Study participating centre University Hospital of Wales

Heath Park Cardiff United Kingdom CF14 4XW

# Study participating centre Hull Royal Infirmary

Anlaby Road Hull United Kingdom HU3 2JZ

# Study participating centre

#### Royal Devon and Exeter Hospital

Royal Devon & Exeter Hospital Barrack Road Exeter United Kingdom EX2 5DW

# Study participating centre Sunderland Royal Hospital

Kayll Road Sunderland United Kingdom SR4 7TP

#### Study participating centre South Tyneside District Hospital

South Tyneside District Hospit Harton Lane South Shields United Kingdom NE34 OPL

### Study participating centre St George's Hospital

Blackshaw Road Tooting London United Kingdom SW17 0QT

# Study participating centre

University Hospital Southampton NHS Foundation Trust

Tremona Road Southampton United Kingdom SO16 6YD

### Study participating centre University Hospitals of Leicester NHS Trust

Leicester Royal Infirmary Infirmary Square Leicester United Kingdom LE1 5WW

# Study participating centre Great Ormond Street Hospital for Children NHS Foundation Trust

Great Ormond Street London United Kingdom WC1N 3JH

### Study participating centre Nottingham University Hospitals NHS Trust

Trust Headquarters Queens Medical Centre Derby Road Nottingham United Kingdom NG7 2UH

# Study participating centre Victoria Hospital

Hayfield Road Kirkcaldy United Kingdom KY2 5AH

#### Study participating centre Royal Hospital for Children and Young People

50 Little France Crescent Edinburgh Lothian United Kingdom EH16 4TJ

# Study participating centre The Royal Free Hospital

Pond Street London United Kingdom NW3 2QG

#### Study participating centre Royal Manchester Children's Hospital

Oxford Road Manchester United Kingdom M13 9WL

# Study participating centre Mid and South Essex NHS Foundation Trust

Broomfield Hospital Chelmsford United Kingdom CM1 7ET

#### Study participating centre

County Durham and Darlington NHS Foundation Trust

Darlington Memorial Hospital Hollyhurst Road Darlington United Kingdom DL3 6HX

#### Study participating centre University Hospitals Bristol and Weston NHS Foundation Trust

Trust Headquarters Marlborough Street Bristol United Kingdom BS1 3NU

# Study participating centre

Cambridge University Hospitals NHS Foundation Trust

Cambridge Biomedical Campus Hills Road Cambridge United Kingdom CB2 0QQ

#### Study participating centre University Hospitals Plymouth NHS Trust

Derriford Hospital Derriford Road Derriford Plymouth United Kingdom PL6 8DH

# Study participating centre Norfolk and Norwich University Hospitals NHS Foundation Trust

Colney Lane Colney Norwich United Kingdom NR4 7UY

### Study participating centre Maidstone and Tunbridge Wells NHS Trust

The Maidstone Hospital Hermitage Lane Maidstone United Kingdom ME16 9QQ

# Study participating centre Birmingham Women's and Children's NHS Foundation Trust

Steelhouse Lane Birmingham United Kingdom B4 6NH

# Study participating centre

East Kent Hospitals University NHS Foundation Trust

Kent & Canterbury Hospital Ethelbert Road Canterbury United Kingdom CT1 3NG

#### Study participating centre

# University Hospitals of North Midlands NHS Trust

Newcastle Road Stoke-on-trent United Kingdom ST4 6QG

# Sponsor information

#### Organisation

Alder Hey Children's NHS Foundation Trust

#### **ROR**

https://ror.org/00p18zw56

# 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

The datasets generated during and/or analysed during the current study are/will be available upon request after an approach to the chief investigator Prof. Daniel Perry (danperry@liverpool. ac.uk). All data requests will be considered by the trial management group and trial steering committee and/or the Oxford Trauma and Emergency Care Senior Leadership Group.

# IPD sharing plan summary

Available on request

#### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
<u>Protocol file</u>	version 2.0	27/08/2024	09/10/2024	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes