

Operative or non-surgical treatment of Perthes' disease

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Registration date 02/08/2024	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 17/03/2026	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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

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Contact details

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Additional identifiers

Clinical Trials Information System (CTIS)

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 36 months 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

Total final enrolment

0

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

England

L12 2AP

Study participating centre

The James Cook University Hospital

Marton Road

Middlesbrough

England

TS4 3BW

Study participating centre

Leeds Children's Hospital

Beckett Street

Leeds

England

LS9 7TF

Study participating centre

Musgrove Park Hospital (taunton)

Musgrove Park Hospital

Taunton

England

TA1 5DA

Study participating centre

John Radcliffe Hospital

Headley Way
Headington
Oxford
England
OX3 9DU

Study participating centre

Peterborough City Hospital

Edith Cavell Campus
Bretton Gate
Bretton
Peterborough
England
PE3 9GZ

Study participating centre

Royal Aberdeen Children's Hospital

Westburn Drive
Aberdeen
Scotland
AB25 2ZG

Study participating centre

Royal Berkshire Hospital

Royal Berkshire Hospital
London Road
Reading
England
RG1 5AN

Study participating centre

Royal Alexandra Children's Hospital

Eastern Road
Brighton
England
BN2 5BE

Study participating centre

Royal National Orthopaedic Hospital

Brockley Hill

Stanmore
England
HA7 4LP

Study participating centre
The Royal Victoria Infirmary

-
Newcastle upon Tyne
England
NE1 4LP

Study participating centre
Sheffield Childrens Hospital

Western Bank
Sheffield
England
S10 2TH

Study participating centre
University Hospital (coventry)

Clifford Bridge Road
Coventry
England
CV2 2DX

Study participating centre
University Hospital of Wales

Heath Park
Cardiff
Wales
CF14 4XW

Study participating centre
Hull Royal Infirmary

Anlaby Road
Hull
England
HU3 2JZ

Study participating centre
Royal Devon and Exeter Hospital
Royal Devon & Exeter Hospital
Barrack Road
Exeter
England
EX2 5DW

Study participating centre
Sunderland Royal Hospital
Kayll Road
Sunderland
England
SR4 7TP

Study participating centre
South Tyneside District Hospital
South Tyneside District Hospit
Harton Lane
South Shields
England
NE34 0PL

Study participating centre
St George's Hospital
Blackshaw Road
Tooting
London
England
SW17 0QT

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

Study participating centre
University Hospitals of Leicester NHS Trust
Leicester Royal Infirmary

Infirmery Square
Leicester
England
LE1 5WW

Study participating centre
Great Ormond Street Hospital for Children NHS Foundation Trust
Great Ormond Street
London
England
WC1N 3JH

Study participating centre
Nottingham University Hospitals NHS Trust
Trust Headquarters
Queens Medical Centre
Derby Road
Nottingham
England
NG7 2UH

Study participating centre
Victoria Hospital
Hayfield Road
Kirkcaldy
Scotland
KY2 5AH

Study participating centre
Royal Hospital for Children and Young People
50 Little France Crescent
Edinburgh
Lothian
Scotland
EH16 4TJ

Study participating centre
The Royal Free Hospital
Pond Street

London
England
NW3 2QG

Study participating centre
Royal Manchester Children's Hospital
Oxford Road
Manchester
England
M13 9WL

Study participating centre
Mid and South Essex NHS Foundation Trust
Broomfield Hospital
Chelmsford
England
CM1 7ET

Study participating centre
County Durham and Darlington NHS Foundation Trust
Darlington Memorial Hospital
Hollyhurst Road
Darlington
England
DL3 6HX

Study participating centre
University Hospitals Bristol and Weston NHS Foundation Trust
Trust Headquarters
Marlborough Street
Bristol
England
BS1 3NU

Study participating centre
Cambridge University Hospitals NHS Foundation Trust
Cambridge Biomedical Campus
Hills Road
Cambridge
England
CB2 0QQ

Study participating centre

University Hospitals Plymouth NHS Trust

Derriford Hospital

Derriford Road

Derriford

Plymouth

England

PL6 8DH

Study participating centre

Norfolk and Norwich University Hospitals NHS Foundation Trust

Colney Lane

Colney

Norwich

England

NR4 7UY

Study participating centre

Maidstone and Tunbridge Wells NHS Trust

The Maidstone Hospital

Hermitage Lane

Maidstone

England

ME16 9QQ

Study participating centre

Birmingham Women's and Children's NHS Foundation Trust

Steelhouse Lane

Birmingham

England

B4 6NH

Study participating centre

East Kent Hospitals University NHS Foundation Trust

Kent & Canterbury Hospital

Ethelbert Road

Canterbury

England

CT1 3NG

Study participating centre
University Hospitals of North Midlands NHS Trust
Newcastle Road
Stoke-on-trent
England
ST4 6QG

Study participating centre
The Robert Jones and Agnes Hunt Orthopaedic Hospital NHS Foundation Trust
Gobowen
Oswestry
England
SY10 7AG

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?
Protocol file	version 2.0	27/08/2024	09/10/2024	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes