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Operative or non-surgical treatment of Perthes' disease

Submission date
29/07/2024

Recruitment status
Recruiting

Registration date
02/08/2024

Overall study status
Ongoing

Last Edited
18/06/2025

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
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

Study website
https://www.opnonstop.org

Contact information

Type(s)
Public, Scientific

Contact name
Prof Daniel Perry

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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

Secondary outcome measures
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

Overall study start date
01/10/2023

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

Age group
Child

Lower age limit
5 Years

Upper age limit
12 Years

Sex
Both

Target number of participants
Planned Sample Size: 216; UK Sample Size: 216

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
England

Scotland

United Kingdom

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

Study participating centre
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 0PL

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

Sponsor details
Alder Hey Hospital
Eaton Road
West Derby
Liverpool
England
United Kingdom
L12 2AP
+44 (0)151 252 5570
research@alderhey.nhs.uk

Sponsor type
Hospital/treatment centre

Website
http://www.alderhey.nhs.uk/

ROR
https://ror.org/00p18zw56

Funder(s)

Funder type
Government

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

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
31/05/2030

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