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Timing of Surgical Intervention for Developmental Dysplasia of the Hip

Submission date
31/07/2014

Recruitment status
Stopped

Registration date
31/07/2014

Overall study status
Stopped

Last Edited
09/11/2017

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Developmental dysplasia of the hip, also known as DDH, is the medical term used to describe looseness and underdevelopment of the hip joint. It occurs when the ball at the top end of the thigh bone does not sit properly within the hip socket. DDH affects thousands of children each year, and ranges from mild hip instability to complete dislocation of the hip. There is no single cause but children born in the breech position and those with a family history of DDH are most at risk. The most effective treatment for children with DDH is carried out in the first 3 months of life with the application of a harness or splint which is applied for a period of weeks. Unfortunately, not all children respond to this treatment and some with this condition are not diagnosed until much later than 3 months. These children are therefore treated differently and need a hip plaster cast with or without the need for an operation beforehand. If an operation is required, this means having a general anaesthetic and a short stay in hospital, in addition to the plaster cast. Doctors are not certain whether it is best to treat straight away or wait until later, usually nearer 12 months of age. As we do not know whether it is better to treat earlier or later, we need to compare the two groups of children in this study. This study plans to find out what is the best time to treat these children.

Who can participate?
Children aged 3 to 13 months diagnosed with hip displacement requiring an operation.

What does the study involve?
Children will be randomly allocated to one of two treatments. One groups will receive the treatment earlier (within two weeks of allocating) and the other group receives it later (no later than 13 months). By taking part in this study the childs hips will be monitored regularly as normal during the study. The child will have regular routine x-rays and examinations and parents will be asked some extra questions about how they feel about the treatment they and the child have received. The type of treatment that the child receives will not change from the normal treatment done at hospital, only the timing of the treatment may be different as it will be chosen randomly. Everything that is normally done for this group of children as part of their treatment will remain the same. Parents will also be asked to complete a diary and some questionnaires during the course of the study and all information collected during the study will be completely confidential.

What are the possible benefits and risks of participating?
There are no benefits to a child taking part in this study as the treatment received will be what is normally given to children with this condition. However, by taking part in this study you will be providing valuable information about your personal experience of DDH and this could influence how best to treat children with DDH in the future. There are no real disadvantages in taking part and there are no additional risks. There are, however, the normal potential risks associated with surgery, should a child require surgery as part of their treatment. The childs doctor will be able to address any concerns parents may have about their child having hip surgery and parents should ask as many questions as needed to put their mind at rest. Parents can also access further information on surgery for hip dysplasia via the steps website (http://www.steps-charity.org.uk /) or via the International Hip Dysplasia Institute website (http://hipdysplasia.org/).

Where is the study run from?
The study is run from the following sites in the UK: University Hospital Southampton, Royal National Orthopaedic Hospital (Stanmore), Queens Medical Centre - Nottingham, Royal Victoria Infirmary - Newcastle upon Tyne, Bristol Royal Hospital for Children, The Royal London Hospital - Barts, Great Ormond Street Hospital, Royal Blackburn Hospital - East Lancashire, Sunderland Royal Hospital , Coventry & Warwickshire NHS Trust, Nuffield Orthopaedic Centre, Oxford, Sheffield Childrens Hospital, Royal Devon and Exeter Princess Elizabeth Orthopaedic Centre, Leeds General Infirmary, Leicester Royal Infirmary, Aldery Hey, Plymouth Derriford Hospital.

When is the study starting and how long is it expected to run for?
The study will start in September 2014 and will run until June 2024.

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

Who is the main contact?
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Contact information

Type(s)
Scientific

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Protocol serial number
16882

Study information

Scientific Title
Timing of Surgical Intervention for Developmental Dysplasia of the Hip: a randomised controlled trial

Acronym
Hip 'OP

Study objectives
The principal question being asked is whether intentionally delaying surgery until the appearance of the Ossific Nucleus (ON) protects against the development of Avascular Necrosis (AVN) in children with Developmental Dysplasia of the Hip. It has been hypothesised that as the femoral head is initially entirely cartilaginous (chondroepiphysis) and its blood supply fragile, the cartilaginous femoral head is more susceptible to compression and therefore AVN. With growth a bony femoral head develops, associated with the appearance of an interconnected and mature circulation within it. In this context, therefore, there is an important unresolved therapeutic dilemma. Intentionally delaying intervention until after the appearance of bone in the femoral head, the ON may protect against AVN since circulation is more resilient to compression.

Ethics approval required
Old ethics approval format

Ethics approval(s)
14/NS/0089; First MREC approval date 06/06/2014

Study design
Randomised; Interventional and Observational; Design type: Treatment, Qualitative

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Topic: Children, surgery, orthopaedics; Subtopic: All Diagnoses; Disease: All Diseases

Interventions
A total of 636 children aged 3 13 months with a dislocated hip in the absence of the proximal femoral ossific nucleus will be recruited (318 in each arm). They will be stratified at randomisaton by failed splintage and age at diagnosis (≤10 months or >10 months). Once eligibility for the trial is confirmed randomisation will be via an independent web-based system (TENALEA). Early treatment is within 2 weeks of randomisation. Delayed treatment is after appearance of Ossification Nucleus and no later than 13 months old. Patients will be followed up until 5 years of age, however, consent for longer term follow-up beyond the trial period by collecting routine data from their medical records and Hospital Episode Statistics to determine

the need for subsequent intervention (further surgery, hip replacement, diagnosis of arthritis, etc). We may need to re-consent participants to continue to this follow-up. Long-term follow-up will allow establishment of a cohort to understand the long-term consequences, if any, of these interventions. Consent for long-term follow-up will only be sought after a parent has agreed to enter their child into the trial. Refusal will not affect the patients participation in the main trial.

Intervention Type
Other

Phase
Phase III

Primary outcome(s)
Incidence of avascular necrosis (AVN grade II to IV); Timepoint(s): Post Surgery

Key secondary outcome(s))
1. Health economic evaluation; Timepoint(s): 6 months post surgery
2. Need for second surgery (subluxation, dysplasia, AVN); Timepoint(s): Follow-up visits (post surgery)
3. Quality of life for child; Timepoint(s): Ongoing post surgery (age 2-5 years)
4. Quality of life for main carer; Timepoint(s): Ongoing post surgery (age 2-5 years)

Completion date
30/06/2024

Reason abandoned (if study stopped)
Participant recruitment issue

Eligibility

Key inclusion criteria
1. Children aged 3 to 13 months with either:
1.1. New diagnosis of developmental displacement of the hip
1.2. Failed splintage up to 12 weeks of age
2. Children who require surgical reduction of the hip (open or closed)
3. Children who are fit for surgery the decision to include in the study will be entirely at the discretion of the operating surgeon
4. Parents willing to give consent to treatment, complete questionnaires and follow-up

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
3 months

Upper age limit
13 months

Sex
All

Key exclusion criteria
1. Children older than 13 months
2. Children with neurological or syndromic teratologic dislocation of the hip
3. Children who have had previous surgical treatment for hip dysplasia
4. Children with an existing AVN
5. Children with existing ossific nucleus

Date of first enrolment
06/11/2014

Date of final enrolment
01/01/2016

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
MP131 University of Southampton Clinical Trials Unit
Southampton
United Kingdom
SO16 6YD

Sponsor information

Organisation
Southampton University Hospitals NHS Trust (UK)

ROR
https://ror.org/0485axj58

Funder(s)

Funder type

Government

Funder Name
NIHR Health Technology Assessment Programme - HTA (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/10/2017		Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes