Parent/Guardian Information Sheet

Chief Investigator: Professor Daniel Perry

We would like to invite you and your child to take part in our research study. The study compares two different types of treatment for your child's hip problem.

The study, which is happening at hospitals thoughout the UK, is led by Professor Daniel Perry, a Consultant Children's Orthopaedic Surgeon who specialises in the treatment of Perthes' Disease at Alder Hey Children's Hospital in Liverpool, and Mr Nicolas Nicolaou, who is a Consultant Children's Orthopaedic Surgeon at Sheffield Children's Hospital.

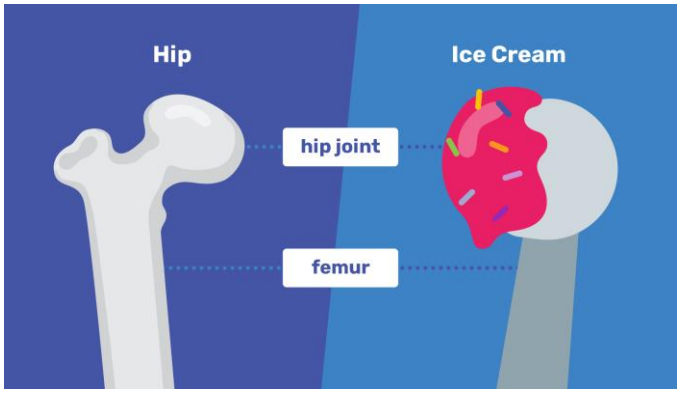
Before you decide to join in, it is important that you understand why we are doing this research study and what it would involve for you and your child. Please visit the study website www.OpNonSTOP.org and watch the video which explains the study. Please also read this information carefully.

Feel free to talk about it with other people. If there is anything that is not clear, or if you would like more information, please ask someone from the research or clinical team.

1) WHAT IS THE OP NON-STOP STUDY?

Op Non-STOP is a research study trying to improve the treatment of children who have a hip condition called Perthes' Disease.

The simplest explanation of Perthes' Disease is to consider the hip like a ball of ice cream (the round hip joint) sitting within an ice cream scoop (the socket).



Perthes' Disease is caused by a temporary problem with the blood supply to the hip, which means the ball doesn't get enough oxygen and nutrients to stay as hard as usual. This means that the hip ball becomes soft (like a melting ice-cream). After some months the blood supply returns, and the hip gets hard again. Problems can occur when the hip ball hardens, because it stays whatever shape it became when it was squashy. This can lead to a hip ball that doesn't fit well into the hip socket, which can cause pain and stop the child doing their usual activities.

The best time to treat the hip in Perthes' disease is when the hip is squashy, which is the stage that your child is currently in. Once the hip becomes hard, the treatment options change.

In the UK, about half of the surgeons treat children affected by Perthes' disease with 'active containment'. Active containment is a package of care that involves physiotherapy, activity restriction, education and pain relief. The specific 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'.

The other half of surgeons treat children affected by Perthes' disease with 'surgical containment.' Surgical containment involves an operation to break the bone to re-orientate the hip. Surgery involves reorientating either the thigh bone (femur) or the hip bone (pelvis). This means that the 'ice-cream ball' changes position in the 'ice cream scoop', to make the hip squash into the round shape of the socket.

As there are currently two options for treatment of Perthes, this study will compare these two treatments for Perthes' Disease in a group of 216 children:

1. 'Active containment' - physiotherapy, activity restriction, education and pain relief.
2. 'Surgical containment - surgery to reorient the ball and socket of the hip.

The best way to fairly compare these different treatment approaches is to create two groups of children who are similar. You can't choose the treatment, and neither can the doctors. This is done through a study process called randomisation. Randomisation means that your child's treatment will **be allocated fairly, at random, to either receive active containment or containment surgery.**

Your child has Perthes' Disease, and the doctors in your hospital would like to invite your child to take part in the study. They are happy to discuss the reasons why this study is appropriate for your child on an individual basis. You are free to decide whether or not you wish for your child to take part. The research team are happy to answer any questions that you may have.

2) WILL THERE BE EXTRA TESTS?

No, there are no additional tests. The study compares the two treatments commonly used in the NHS.

3) ARE THERE ANY RISKS IN TAKING PART?

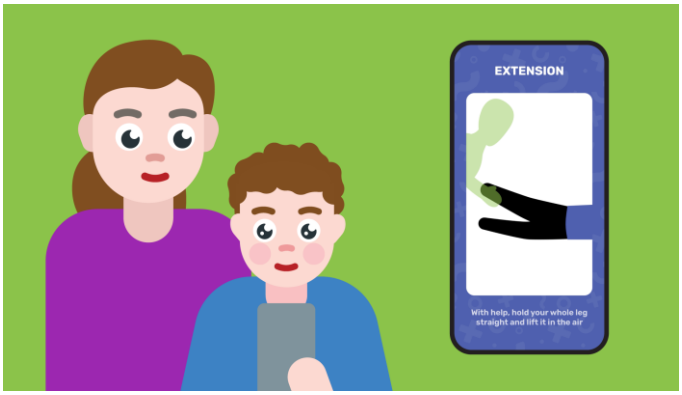
Each of these treatments have potential advantages and disadvantages.

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 requires children and their families who are affected by Perthes' disease to engage with therapy at home, with support from the physiotherapists. Despite the hard work done by children and their families in taking part in therapy, the hip may not grow into a normal round shape, which could cause pain and arthritis, which may increase the chance of requiring surgery in the future.
2. Surgical containment is done by carefully repositioning 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. 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.

4) WHAT DOES THE STUDY INVOLVE?

If you decide you would like your child to take part in this study, 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.



If you are allocated to active containment

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 from 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. You do not have to agree to this and can decline to have the session recorded if you wish. The recording will be anonymised and will be deleted 12 months after the research team checks it.

If you are allocated to surgical containment

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 repositioned. 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 cast' (a plaster cast worn around the hips, down to the knees) and they 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 metal implants used to hold the bones in position.

Follow-Up

During the research study, we will have brief contact with you by text message and/or email on eight further occasions (3 months, 6 months, 9 months, 12 months, 18 months, 24 months, 30 months and 36 months after enrolment). We will ask questions about pain, activities, how your child feels, hospital attendances, school attendance and costs that you may have incurred in relation to this hip problem (i.e. days absent from work etc.). It is important that you try and complete the questionnaires with your child as soon as possible after they are received. If the questionnaire is not completed, we will give you a reminder after a few days (by phone, text or e-mail based on your preference) and will send a reminder to the secondary contact (if details present). If it is not completed after one week, we may call you to ask the questions over the telephone. We would like to offer you a £10 voucher at the end of each year to compensate you for costs (i.e. mobile phone data) incurred whilst completing the questionnaires.

Your child will be given a unique study identification number which will be used for all of the information we collect from you about your child.

For all children, we collect routinely taken x-rays (radiographs) of the hips for analysis.

NON-ARTHROPLASTY HIP REGISTRY

To help us to find out which operations work best and monitor longer term well-being, hip surgeons keep records of their patients on a national database called the Non-Arthroplasty Hip Registry (NAHR). We'd like to ask you if we could share your personal details with the NAHR. Personal details need to be stored in this registry in order to link your child to their surgery and, if in the future, they need any further hip surgery. The personal information stored includes name, gender, date of birth, telephone number, postal address, email address and NHS number. The registry will store information about your child's hip problem and the treatment that they received (this is classed as sensitive personal information under the Data Protection Act). More information can be found here: www.nahr.co.uk. Please note that this additional aspect of the study is optional.

5) WHO HAS FUNDED THE STUDY?

The study is funded by the National Institute for Health and Care Research (NIHR) Health Technology Assessment (HTA) Programme (Reference NIHR152309)

6) WHO IS INVOLVED WITH THE STUDY?

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.

7) WHO HAS APPROVED THE STUDY?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to help to support participants' interests. This study has been reviewed and been given a favourable opinion by West Midlands - Black Country Research Ethics Committee.

8) HOW WILL THE INFORMATION COLLECTED BE HANDLED?

Data protection regulation requires that we state the legal basis for processing information about you. In the case of research, this is 'a task in the public interest'. The University of Oxford and Alder Hey Children's NHS Foundation Trust are the main data controllers and are responsible for looking after your information and using it properly. The British Hip Society is the data controller for any personal information held in the Non-Arthroplasty Hip Registry (NAHR). Bangor University are responsible for processing and analysing de-identified data relating to the health economic analysis.

We will be using information from you, your child and their medical records in order to undertake this study and will use the minimum personally-identifiable information possible. The data collected will be stored securely in a de-identified (pseudonymised) form. Your treating hospital will collect information from you, your child and/or your child's medical records for this research study in accordance with our instructions.

In order to contact you during the study, we will collect contact details for youand a potential secondary contact. These will be stored for 12 months after completion of the study.

A copy of your consent form and your child's *assent form (**if completed*) will be stored at your treating hospital for up to 12 months after the youngest participant in the study reaches the age of 21 years. They

will also be stored in your childs medical records, as per local hospital policy and by the University of Oxford for 12 months after completion of the study.

Yours and your child's personally identifiable information and contact details will be stored separately to the data collected for the study.

The University of Oxford and your treating hospital will use your name, health record number (e.g. NHS/CHI/H&C number) and contact details to contact you about the research study, and to make sure that relevant information about the study is recorded for your care. Individuals from the University of Oxford, Alder Hey Children's NHS Foundation Trust and regulatory organisations may look at your child's medical and research records to check the accuracy of the research study. Your treating hospital will pass these details to the University of Oxford along with the information collected from you, your child and/or their medical records.

The only people who will have access to information that identifies either of you will be people who need to contact you, to enable your follow-up in this study, or audit the data collection process. The people who analyse the information will not be able to identify you, or your child, and will not be able to find out your name, health record number or contact details.

We may disclose your personal data to our third-party service providers to carry out activities specifically for the purpose of this research and as explained in this information sheet. For participants allocated to the 'Active Containment' group this will include disclosing of personal data (first name and study number) to facilitate the use of the digital app. Any third-party service providers are required to take appropriate security measures to protect your personal data in line with University of Oxford policies. We do not allow our third-party service providers to use your personal data for their own purposes, but rather to only process your personal data for specified purposes and in accordance with our instructions.

9) CAN MY CHILD STOP TAKING PART IN THE STUDY?

You or your child can change your mind at any time and can contact the research team by email at OpNon-STOP@ndorms.ox.ac.uk. Leaving the Op Non-STOP study will not change the level of care your child will receive.

If you withdraw your child from the study, your child's study participation will end, and the study team will stop collecting information from you. Information collected up until your child's withdrawal from the study will continue to be used and included in the study.

10) WHERE CAN I FIND OUT MORE ABOUT HOW MY INFORMATION IS USED?

You can find out more about how we use your information:

- From the Op Non-STOP website: www.OpNonSTOP.org
- By contacting the Op Non-STOP study team at Oxford: OpNon-STOP@ndorms.ox.ac.uk
- By asking a member of the research team at your treating hospital
- In the Health Research Authority leaflet available from www.hra.nhs.uk/patientdataandresearch
- By contacting the University of Oxford Data Protection Officer on data.protection@admin.ox.ac.uk
- By contacting Alder Hey Data Protection Officer on dpo@alderhey.nhs.uk
- By contacting the NAHR Data Protection Officers on dpo@nahr.co.uk
- From the NAHR website www.nahr.co.uk or by emailing customer.support@amplitude-clinical.com

If you are not happy with the way your information is being handled, or with the response received from us, you have the right to lodge a complaint with the Information Commissioner's Office at Wycliffe House, Water Lane, Wilmslow, SK9 5AF: https://ico.org.uk/

11) RIGHTS TO ACCESS YOUR INFORMATION

Data protection regulation provides you with control over your personal data and how it is used. When you agree to your information being used in research, however, some of those rights may be limited in order for the research to be reliable and accurate.

Further information about your rights with respect to your personal data is available at https://compliance.web.ox.ac.uk/individual-rights

12) INFORMATION SHARING FOR OTHER RESEARCH

When you agree for your child to take part in a research study, the information about their health and care may be provided to researchers running other research studies in this organisation and in other organisations. These organisations may be universities, NHS organisations or companies involved in health and care research in this country or abroad. This information will only be used by organisations and researchers to conduct research in accordance with applicable regulations or for related teaching purposes.

This information will not identify your child and will not be combined with other information in a way that could identify them. The information will only be used for the purpose of health and care research, and cannot be used to contact you or to affect their care. It will not be used to make decisions about future services available to them, such as insurance.

13) WILL WE BE INFORMED OF THE RESULTS OF THE STUDY?

The study is registered on the clinical trial registry, ISRCTN83315571, which can be accessed at this website: https://www.isrctn.com/ISRCTN83315571

The study results will be available to you at the end of the study at www.OpNonSTOP.org. All results will be de-identified, meaning that no one can identify you or your child from the results directly.

14) WHAT IF THERE IS A PROBLEM?

If you wish to discuss any aspect of the way in which you have been approached or treated during the course of this study, you should contact Professor Daniel Perry who is the overall study lead on 0151 228 4811 or email OpNon-STOP@ndorms.ox.ac.uk, or you may contact the Sponsor at Alder Hey Children's NHS Foundation Trust on 0151 252 5570 or email research@alderhey.nhs.uk.

Every care will be taken in the course of this clinical study. However, in the unlikely event that your child is harmed by taking part in this research study, there are no special compensation arrangements. If your child is harmed and this is due to someone's negligence, then they may have grounds for a legal action for compensation against the NHS Trust where they are being treated but you may have to pay legal costs. The normal National Health Service complaints procedures should be available to you and your child.

For independent advice, please contact NHS Complaints. Ask your treating hospital for the contact details or visit https://www.nhs.uk/using-the-nhs/about-the-nhs/how-to-complain-to-the-nhs/. This is a confidential NHS service that can provide you with support for any complaints or queries you may have regarding the care you receive as an NHS patient. However, they cannot provide information about this research study.