

## Research Study

### “Risk factors for hip dysplasia in newborns”

We would like to invite your child to be part of a research study taking place at **Great Ormond Street Hospital for Children** and **University College London Hospitals**. The study is being led by a team of doctors, scientists, and research nurses. A group of parents of children with hip dysplasia have also given advice on how this study should be conducted. These parents will continue to be involved in the study.

We conducted a previous study between 2009 and 2013, which you consented for your child to participate in. At the time you consented to being contacted about further research, and we would like to invite you and your child to participate in this new study.

Please take time to read the following information. Talk to others about the study if you wish. We will telephone you in a week or so when you can ask us any questions about the study.

This information leaflet will give you an idea about our study and what we would ask from you if you decide that you and your child will participate.

**What is hip dysplasia?** Some newborns are at risk of developing a disease called “congenital hip dysplasia”, which affects the growth of the hip. It can cause problems at different stages of life. Sometimes the disease is noticeable at birth and the newborn will receive treatment immediately. However, sometimes the disease develops slowly and is not found until the child first feels pain, which can be as late as adolescence. It is estimated that 29% of all adults who have hip replacement surgery need it because of congenital hip dysplasia.

Our study wants to find out which newborns are at risk of developing this hip disease so that doctors can give special attention to these children. Doctors can then give earlier treatment, before the hip becomes painful. This will save the hip from wearing out at a young age. It will minimize the risk of needing a hip replacement operation in adult life.

**What is the study about?** Babies may have some characteristics (doctors call them “risk factors”) that show that they are more likely to develop hip dysplasia. For example, it has been suggested that a child is more likely to get hip dysplasia if a parent or sibling also has it. Girls may be more at risk than boys. Another ‘risk factor’ is being born with a foot problem. These kinds of characteristics can suggest to doctors that a child might have hip dysplasia, and an X-ray or ultrasound test is needed to check for the disease.

We wish to find out which are the most important risk factors, and how much they increase the risk of hip dysplasia. We would like to know what happens if a baby has more than one of these characteristics. We want to find out which features indicate that newborns will have hip dysplasia at the age of 2 years or more.

Understanding which factors place a newborn at high risk for this hip disease will enable the NHS to make sure that infants at risk will receive the care they need. For example, doctors could pay special attention to such infants when they are newborns. They could book them for X-rays to check that their hips are developing well. This would speed up diagnosis and treatment where needed. It would also avoid lengthy and complicated treatments, which are necessary in those diagnosed late (at school age or in adolescence).

**Why has my child been invited to participate in this research?** We know from a previous study and your child's medical records that your child had 1 or more risk factors for hip dysplasia when she or he was born. We are inviting all parents of children with a risk factor to participate in this study. Having a risk factor does not mean a child will develop hip dysplasia. But some infants are normal soon after birth, and develop hip dysplasia later.

For this reason, we wish to bring back all babies who we know had one of these risk factors. We want to check that their hips are normal by doing 1 X-ray of both hips. **Getting as many participants as possible in the study will help to improve the quality of the study and to give confidence in the results. Every child that participates is important.**

**What will happen if I decide to take part?** We will contact you by telephone a week after you have received this letter to ask if you are interested to participate, and to answer any questions you may have about the study. If you decide to participate, we will arrange a convenient appointment for your child to have 1 X-ray of the hips taken at the hospital. An x-ray is the best way of finding out if there is dysplasia or not. This will be done at University College Hospital (UCLH). If you cannot come to UCLH, we will try arranging the X-ray for you at a hospital that is more convenient for you.

When you come to UCLH a member of the research team will meet you to obtain written informed consent. You will also have the opportunity to meet a nurse or a doctor who is a bone specialist. You can ask them any questions about your child. If necessary, they will be able to examine your child's feet, legs, or the way your child walks. They will tell you if the X-ray was normal or not.

If your child has the X-ray at a hospital closer to home, a nurse practitioner will meet you and your child at home to obtain written informed consent, or we will take consent over the telephone.

**What happens if the X-ray is not normal?** Whilst we expect that the majority of X-rays will show normal hips, there will be some that will show hip disease and this will be new information for the parents. If this happens, the nurse will tell you about it on the day. She will also arrange for you an appointment with a consultant and, with your consent, inform your GP about it. As we will have found the hip disease while the child is still young, the outlook for the child is good. We will not need to rush treatment. However, your child may remain under the care of the consultant. The consultant will discuss with you what exactly the X-ray shows and what the best options are for your child.

**What happens if the X-ray is normal?** If the X-ray is normal, we do not need to do anything and you can be certain that your child's hips are normal and will stay normal throughout growth.

**How long will it all take?** Please allow 1 hour for all this. You will need to check in, go to X-ray and see the nurse. All will happen in the same clinic area. The X-ray will take 2-5 minutes, whilst the nurse appointment will take a little longer.

**Potential harms (injury, discomforts, or inconvenience).** Your child will have an X-ray of the hips. X-ray is the best way of finding out whether there is a problem. The risk associated with this X-ray is very small and it should not cause any harm or problems. The time required to attend the appointment (no longer than an hour) might be an inconvenience.

**Potential benefits.** Your child will have an X-ray of the hips, followed by a consultation with the nurse. When you meet the nurse she will discuss the results of the X-ray with you. Also, she will discuss any other concerns that you may have, such as concerns about your child's walk, or the shape of their feet or knees. You can ask any questions. If the nurse cannot help you she will write to your GP and initiate a referral of your child to a specialist if appropriate.

**A great benefit is that the X-ray will let you know how your child's hips are developing. If there are any problems, we will ensure that your child sees a consultant quickly. As well as checking the health of your own child, you will be helping future babies who will benefit from this study.**

**Long-term follow-up of children.** There are very few long-term studies of babies that have been born with risk factors for hip dysplasia. All children who participate in this study could help in future

studies. For example, we may want to plan another study that re-examines all children when they are teenagers just to see how they are getting on with their hips. We will ask you if we can contact you or your child again in the future should any new research be done. If you agree to be contacted, you won't be under any obligation to take part.

**Confidentiality.** Confidentiality will be respected and no information that discloses your identity will be released or published without consent unless required by law. The law requires us to report any suspected cases of child abuse. For your information, the original research consent form will be inserted in the patient chart and a copy will be given to you. We will also send a letter to your GP, with your consent, informing them about your child's participation in the study. Should any other findings be seen on your child's x-ray that require further investigation, the Consultant will make the necessary referrals.

**Participation.** Participation in this study is voluntary. If you choose not to participate, or if you withdraw your child from the study at any time, this will not impact on any future care your child receives.

**What if there is a problem?** You can tell member of the study team, like the nurse or your GP. Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be examined. In addition you can seek advice from the Patient Advice and Liaison Office (PALS) at Great Ormond Street Hospital, which provides free confidential service to help patients, parents and carers with any information, concerns, or problems that they have about their NHS care/service. You can contact PALS on 020 7829 7862 or email: [pals@gosh.nhs.uk](mailto:pals@gosh.nhs.uk)

### **Who is organizing this research and how will the results be disseminated?**

The study is funded by a Research for Patient Benefit Grant awarded from the National Institute for Health Research and conducted at Great Ormond Street Hospital, UCLH and Institute of Child Health. Results of this study will be published in scientific journals but participants will not be identified in any report/publication. A copy of the results will be sent to all participants at the end of the study in the form of a Newsletter. The Camden and Islington Ethics Committee has approved the study.

**Questions and further information.** This study is led by Dr Andreas Roposch, who is a consultant orthopaedic surgeon and scientist. He practices at Great Ormond Street Hospital but works also at UCLH. His telephone number is 020 7813 8451/020 7905 2134. For more general information about hip dysplasia we suggest looking up the STEPS Charity's website [www.steps-charity.org.uk](http://www.steps-charity.org.uk) or phoning them at 01925 750271.

**Thank you for taking the time to read this information sheet. We hope you will be able to take part in our research. It may help your child and it will definitely help many more newborns and children in the future.**