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CPinBOSS PARENT/GUARDIAN INFORMATION SHEET

Information for Adults

Cerebral Palsy in the British Orthopaedic Surgery Surveillance Study (CPinBOSS)

Understanding surgical treatment for patients with Cerebral Palsy.

We would like to invite your child to take part in our research study.

The CPinBOSS study is a research study lead by surgeons, physios and scientists who are working to improve the treatment of children and young people who have Cerebral Palsy (CP). This study is part of a wider programme working with other diseases that can affect bones, joints and muscles in children and young people (British Orthopaedic Surgery Surveillance Study - BOSS).

We'd like to invite your child to be involved as the clinicians think they would benefit from surgery. This is a "cohort study" which means that we follow your child's condition closely over the next 2 years and hopefully into the future.

The study team works at the University of Oxford and at Oxford University Hospitals NHS Trust.
Before you decide if your child can take part, we would like you to understand why the research is being done and what it would involve for you and your child. Please take the time to read the following information carefully. Discuss it with friends and relatives if you wish. You are free to decide whether or not you wish for your child/relative's information to be used. Your decision will not affect the care your child/relative receives.

The Facts and the Questions

- Your child has been assessed by the clinicians who believe your child would benefit from an operation to help with their walking and function
- This operation is routinely done on children with CP in the UK and across the world
- However, we would like to know more about the operation and how children do afterwards
- This is an observational study, which means we wish to closely monitor your child over the course of their treatment without changing any part of the care given
- Your child will be asked to complete some questions about pain, activities and feelings. These questions will be asked at the beginning of the study, an on regular occasions up to two years from now
- Your child's details (i.e. NHS number) will be kept securely to enable researchers to contact your child in the distant future to find out more about their CP.

How to contact us:
Site PI name and contact details

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What will we find out?

- How many patients have SEMLS procedures
- How they do afterwards
- How to improve treatments for children and young people with CP.

We cannot guarantee that your child will get any direct benefit from taking part in this study. However, your child taking part will help us to explore CP surgery, which may lead to better care and outcomes in the future.

The treatment and care that your child will receive is the same whether they take part in the study or not. You will be asked to complete some short questionnaires in addition to routine hospital treatments.

This study does NOT involve any extra tests or visits to the hospital!

Why does there need to be a study?

- Cerebral Palsy (CP) is the most common physical disability in childhood.
- Diplegia is the form of CP that mostly involves the legs and affects movement, walking and function.
- Some children with CP may use supports to help with walking and function.
- SEMLS surgery aims to improve problems with bones, joints and muscles. This involves one operation and one period of rehabilitation.
- Across UK hospitals, there are differences in the type of patients who have SEMLS and differences in the procedures performed within SEMLS.
- Recent evidence suggests SEMLS is very successful and ideally more patients could benefit from this treatment.
- To help us understand we would like to collect data about patients, their treatment and how they feel afterwards.

Your hospital is one of many hospitals taking part in this study across the country. We hope to involve as many children and young people with CP who are having SEMLS surgery as we can.

What does the study involve?

- The doctors and their teams at your hospital will collect information about your child's treatment over a 2 year period (i.e: what treatment they have, what this involves and if there were any complications)
- Information about their routine clinical assessments and treatments (i.e: Gait Analysis scores, Surgical procedures) will also be collected throughout the 2 year period.
    - This information is part of a national service evaluation
- With your consent you and your child will receive questionnaires via email or post, if you prefer, about how your child is getting on.
    - These questionnaires are part of a cohort study
- Even if you and your child decide not to go ahead with the surgery we would still like to send questionnaires to see how your child is getting on.
- There is no payment to patients involved in this study.
- The study results will be made available on the study website when the study is finished: www.ndorms.ox.ac.uk/cpinboss

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Consent
We will ask you to sign a consent form, indicating you agree to your child taking part in the study.
To do this, we will send you a link via email and you can agree to participation electronically.
Alternatively, you may sign a paper consent form.
We don't mind which way you chose!

If you agree to your details being held to be contacted regarding future research, we will retain a copy of your consent form until such time as your details are removed from our database but will keep the consent form and your details separate.
Agreeing to be contacted does not oblige you to take part in future research, and you can be removed from this register at any time you wish.

What will happen if I don't want to carry on with the study?
If you do not agree for your child/relative to be part of this study, this will not change the care they will receive. You can change your mind at any time and can contact the research team using the contact details on the last page of this sheet.

What if there is a problem?
If you have a concern about any aspects of the CPinBOSS study, you should speak with your clinical/research team at your hospital. They will do their best to answer your questions

Site PI name and contact details

The University of Oxford, as Sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your participation in this study.

If you remain unhappy and wish to complain formally you can contact your local team (details above), or you may contact the University of Oxford Clinical Trials and Research Governance (CTRG) office on 01865 616480, or the head of CTRG, email ctrg@admin.ox.ac.uk.
The Patient Advisory Liaison Service (PALS) 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. PALS is unable to provide information about this research study.

Will taking part in the study be kept confidential?
Yes, only the study team and members of your clinical care team will know about you taking part in the study. When you consent, your details will be passed to the study team in Oxford so they can send you questionnaires. This includes name, address, telephone number and/or email address. A study identification number will be given to the participant when consent is given. All personal information will be stored in a secure database at the University of Oxford.

12 months after the study ends, identifiable information will be discarded appropriately. Only de-identified information will be kept. This means only information with the study identification number is kept.

Responsible members of the University of Oxford [and the relevant NHS Trust(s)] may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations.

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Who is involved with the study?

- A group of surgeons, physiotherapists and scientists who have many years of experience with working with children and young people with CP.
- They work with the Surgical Intervention Trials Unit (SITU) in Oxford who will help manage the project. The SITU team have experience with surgical research.
- The study is funded by a grant from the Action Medical Research, a charity that supports research involving children and young people.
- The study is sponsored by the University of Oxford and has been reviewed by your local hospitals Research department.
- We will be using information from you and your medical records in order to undertake this study and will act as the data controller for this study.
- The study has also been reviewed by a research ethics committee, who have agreed the study is being conducted in a correct and appropriate manner.

CPinBOSS Team
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How will information about my child/relative be used?

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 is the data controller and is responsible for looking after your information and using it properly.

We will be using information from you and your medical records, and will use the minimum personally-identifiable information possible. We will keep identifiable information about you for one year after the study has finished. This excludes research documents with personal information, such as consent forms, which will be held securely at the University of Oxford for 5 years after the end of the study.

The local NHS Trust will use your details, e.g. name, NHS number, home address, and contact details to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. They will keep identifiable information about you from this study for 12 months after the study has finished, and a copy of your consent form will remain in your medical records for as long as these are held.

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 http://www.admin.ox.ac.uk/councilsec/compliance/gdpr/individualrights/