



Participant Information Sheet For Parent Participants

Study of Outcome of Childhood Stroke (SOCS)

www.childstroke.org.uk

A prospective, population based study of the epidemiology and outcome of stroke in childhood.

You and your child are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends, relatives or your GP if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of the study?

A stroke can be thought of as a “brain attack”. A stroke is what happens when the blood supply to part of the brain is cut-off. This can damage the part of the brain no longer supplied by blood. The damaged area of brain may no longer be able to function properly. Any of the brain’s many functions may be affected. For example, the brain may no longer be able to properly control limb movements or speech.

Most people affected by stroke are adults. However, some children are affected by strokes as well. The purpose of this study is to find out how many children are affected by stroke and how many children with a stroke will have more strokes. The study also aims to find out how stroke can affect children’s movement, intelligence, behaviour and quality of life. Finally, the study aims to contribute to an international anonymous database of stroke in children.

Why have I been chosen?

You are being invited to take part in this study because your doctor has diagnosed a stroke in your child. The study aims to invite all children affected by stroke and their parents who live in the south of England to participate. We estimate that we will ask 200 children to take part in 1 year.

Do I have to take part?

No, taking part is voluntary. If you decide not to take part you do not have to give a reason, no one will be upset and the standard of care that your child receives will not be affected. If you do decide to take part we will ask you to sign a consent form for yourself and for your child. We will give you a copy of this information sheet and the consent form to keep. If you decide to take part you can still withdraw at any time.



What will I be asked to do if I take part?

We would ask that you be involved in the study for 12 – 14 months although you would not need to do anything for most of that period. With your permission, we would record information about your child taken from their medical notes around the time of the stroke. We would record details such as age, ethnicity, blood pressure, blood test results, brain scan results, and treatment given. With your permission, we would also take copies of your child's brain scans. We would also like your permission to take a blood test from your child. The blood would be stored for the future. In the future it may be useful to see if there is anything about a child's genetic makeup that means they are more likely to have a stroke.

We would have no part to play in your child's treatment as this will be done by your own doctor. Participation in the study will not affect your child's treatment in any way.

At 12 – 14 months we would visit you at home to assess how the stroke had affected your child. We would assess your child's motor and movement function, intelligence, behaviour and quality of life through a variety of questionnaires and tests. We would spend about 45 minutes to 1 hour testing your child. We would then interview you, the parents or guardians, for about 1 hour. We will ask you questions about your child's communication, daily living skills, socialisation, and motor skills. We will write down the answers that you give. During that time your child does not need to be present and can rest or play. We would then test your child for a further 45 minutes to 1 hour. With your permission we will film your child doing some of the tests so that we can get an accurate score for those tests. Finally, we would leave some questionnaires for you and your child (if old enough) to complete and post back to us in your own time. The questionnaires for parents will take up to 1½ hours to complete and for children up to 30 minutes to complete. These questionnaires will ask about your child's emotions, communication, health, quality of life and participation in various activities.

No further participation is currently planned but we would like to ask your permission to contact you again in the future to invite you to take part in further research. Any further treatment your child required would still be ongoing through your own doctor.

With your permission we would also enter some of the information collected about your child onto an international database. This database is maintained by the International Paediatric Stroke Study (IPSS). The data entered here is entirely anonymous with no way of identifying individuals from the database. The database is maintained in Canada but doctors from around the world contribute to it. The Chief Investigator for SOCS is part of the core group of people directing IPSS.

What are the possible risks of taking part?

There are no specific risks from taking part in the study as your child's treatment will not be changed by participation. However, your child may find the assessment at the end of the study boring or tiring. If you prefer we can plan to do different parts of the assessments on different days and if you or child would like to stop during the assessments we can finish on another day. The assessments will be conducted by an experienced paediatric doctor. If you agree that we can store a sample of your child's blood it may mean an extra blood test for your child. However, every effort would be made to do the tests along with blood tests your own doctor is doing so that no extra blood tests would be needed.



What are the potential benefits of taking part?

After completing the assessments we can provide you with a detailed analysis of the results of those tests. We hope that the study will provide valuable information that leads to a better understanding of stroke in children and will help to find out the best way to treat children with strokes.

Is my doctor being paid for including my child in the study?

Your doctor will not receive any payment for including your child in this study.

Are there any restrictions on what I might eat or do?

No, participation in the study does not involve any restrictions. However, your doctor may advise treatments or restrictions as part of the management of your child's stroke. This advice will not be altered by participation in this study.

Confidentiality – who will know I am taking part in the study?

The researchers will look at your child's medical records. However, all information that is collected about your child during the course of the research including the video and the answers that you have given to interview questions will be kept strictly confidential. Your child will not be able to be identified from any report that is published. Your child's name and address will not be put on any of the test results or video. With your permission we would let your GP and hospital doctor know that your child is participating in this study.

What will happen to the results of the research study?

The results will not be known until the last child has been assessed in approximately February 2010. The results may be reported in professional publications or meetings but your child will not be identified by name. We will make a summary of the results available on the study website.

Who is funding the research?

This study is being funded by a grant from a charity, the Stroke Association.

Who has reviewed the study?

The National Research Ethics Service (part of the National Patient Safety Agency) has approved the study.

What do I do now?

Thank you for considering taking part in this research. If you agree to participate in this study we will ask you and your child (if appropriate) to complete a participant consent form.

If you would like further information please contact:

Dr. Andrew Mallick, Research Associate, SOCS, Level 6 UBHT
Education Centre, Upper Maudlin Street, Bristol, BS2 8AE
e-mail : mallick@childstroke.org.uk Tel : 0117 3420176