Surgical Trial in Traumatic Intracerebral Haemorrhage: STITCH (Trauma)

A Study of the Treatment of Brain Haemorrhage

Information for Patients

You 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 relatives and friends 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.

Thank you for reading this.

What is the purpose of the study?

Head injury often causes bruising of the brain where blood leaves the blood vessels and enters the brain tissue. The purpose of this study is to find out if surgical removal of bruised areas improves recovery after head injury.

Surgery carries some risks and would not be considered for small bruises which we know recover well. Larger bruises may have a toxic effect on surrounding un-bruised brain and may expand further suggesting that surgical removal can help but we do not know how the risks and benefits of surgery are balanced.

This study is for people with significant bruising of the brain after a head injury. The patients in the study will be divided into two groups. One group will have surgery to remove the blood clots and damaged tissue caused by the bruising and the other group will not. Both groups of patients will be carefully monitored. We will then compare how the two groups recover to see if there is any difference.

Why have I been chosen?

When someone has a head injury with bruising of the brain, surgeons have to make decisions about whether to operate. These decisions can sometimes be complicated. People with minor bruising don't usually need an operation whereas people with severe bruising do need an operation. In this study we only include people between these two extremes. You have been chosen because you have a bruise on the brain caused by a head injury and it is not so small that we don't need to consider an operation and it is not so big that an operation is clearly needed.

Do I have to take part?

It is up to you to decide whether or not you want to take part. If you do not wish to take part in the study your treatment will not be compromised in any way and a decision about the need to have an operation will be taken by the Consultant in charge according to how the situation develops. If you wish to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time without giving a reason. This will not affect the standard of care you will receive. If you withdraw from the study we will need to keep all the data collected up to your withdrawal and we will ask for permission to send you follow-up questionnaires.

What will happen to me if I take part?

All the procedures being carried out in this study are part of routine clinical care. If you agree to take part in the study you will be randomly allocated, by computer, to one of two groups.

One group of patients will receive an immediate operation; the other group of patients will be kept under close observation. If you are in the 'early operation' group, your Consultant will perform an operation to remove the clot from your brain and closely monitor your condition. If you are in the 'non-operation' group, your condition will be closely monitored and you can still receive an operation later, should this become necessary. Whatever group you are allocated to you will receive the best available medical treatment which may include the careful monitoring of pressure inside your skull. In total we hope to recruit 840 patients to this study.

What do I have to do?

Once you have consented to take part in this study details will be collected from your medical notes regarding the treatment you receive and your response to that treatment. You will have already received a head CT scan before you joined the study as part of your routine care and you will be given another head CT scan at around 5 days after your treatment has started so that the study research team can analyse the changes after you have received your treatment. Sometimes your doctors will need to do further additional CT scans however these ones will be for routine clinical reasons.

At three, six and twelve months after you receive your treatment you and/or your family/carers will be sent postal questionnaires asking how you are managing, about your health generally and about your use of health services. These questionnaires will each take approximately 15 minutes to complete and you will be supplied with stamped addressed envelopes to return them to the project office in Newcastle. Before sending the questionnaires we will confirm with your consultant and/or GP whether you have experienced any complications and where you are living.

What is the procedure being tested?

No new procedure is being tested during this study. Both methods of treatment are used routinely.

What are the alternative treatments?

Early surgery and careful observation/monitoring are the two methods used to treat bruising and bleeding in the brain caused by trauma.

What are the risks or benefits of taking part?

The usual possible risks associated with having an operation or being monitored in hospital apply to this study. Your doctor will be able to discuss these with you. We cannot promise that the study will help you, but the information we get might improve treatment of future patients with bleeding inside their brain as a result of an injury.

What if something goes wrong?

If you participate in this study your hospital consultant remains in charge of your medical care. If you wish to complain about any aspect of the way you have been approached or treated during the course of this study you should ask to speak to your consultant or local co-ordinator who will do his/her best to answer your questions and resolve the situation. You can also contact the STITCH (Trauma) research team in Newcastle by telephoning 0191 222 5764 or by writing to: Neurosurgical Trials Unit, 3-4 Claremont Terrace, Newcastle University, Newcastle upon Tyne, NE2 4AE, UK.

In the extremely unlikely event that you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action but you may have to pay for it.

Regardless of this, if you wish to complain formally about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints mechanism is available to you. Details of this can be obtained from your local hospital.

Will my taking part in this study be kept confidential?

All information collected about you or from you will be treated as strictly confidential. All the data is stored by the co-ordinating centre at Newcastle University. The staff at Newcastle will maintain the confidentiality of all the data they store. With your permission they will inform your GP that you are taking part in the study. All data entered on computer for analysis will be coded. The data will be retained for 15 years and then destroyed securely. Identifiable data may be viewed by authorised persons such as researchers, regulatory authorities and Newcastle NHS Trust to check the study is being carried out correctly. All will have a duty of confidentiality to you as a research participant and nothing that could reveal your identity will be disclosed outside the research site or the Neurosurgical Trials Unit at Newcastle University.

What will happen to the results of the study?

It is anticipated that the data from this study will be published in medical journals and also by the funder of the study. When this happens it will be presented anonymously and it will not be possible to identify any individual patient.

Who is funding and organising this study?

This study is funded by the NIHR Health Technology Assessment Programme and is being carried out in other countries around the world as well as in the UK. The study is being co-ordinated by the Neurosurgical Trials Unit, Newcastle University.

Who has reviewed this study?

This study has been reviewed by Southampton and Southwest Hampshire Research Ethics Committee A.

Contact for further details.

If you have any questions about the study please speak to the Local Co-ordinator

Name and contact details of the Local Co-ordinator:

Please retain this sheet for your future information.

Date:

Protocol STITCH(TRAUMA) Version

The UK Clinical Research Collaboration has developed a leaflet "*Clinical Trials: What they are and what they're not"* which answers some of the many questions people have about clinical trials including: Why do we need to do them? Are they safe? What happens at the end of a trial? They have also produced a booklet on "*Understanding Clinical Trials*", which explains what clinical trials are and how and why they are carried out. It is designed to answer the many questions people may have when deciding whether to take part in a trial. They are available from http://www.ukcrn.org.uk/index/patients/publications or UKCRC, 20 Park Crescent, London, W1B 1AL