Surgical Trial in Traumatic Intracerebral Haemorrhage: STITCH (Trauma)

A Study of the Treatment of Brain Haemorrhage

Information for Consultees

Your relative is being invited to take part in a research study. Before you decide if they would wish to take part 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 your relative would 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 has my relative 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. Your relative has been chosen because they 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.

Does my relative have to take part?

It is up to you to decide whether or not your relative would wish to take part. If you do not think they would like to take part in the study their 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 think your relative would be happy to take part you will be given this information sheet to keep and be asked to sign a form. If your relative participates in the study they are still free to withdraw at any time without giving a reason. This will not affect the standard of care they will receive. If they withdraw from the study we will need to keep all the data collected up to their withdrawal and we will ask for permission to send them follow-up questionnaires.

What will happen to my relative if he/she takes part?

All the procedures being carried out in this study are part of routine clinical care. If you indicate that your relative would wish to take part in the study they 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 they are in the 'early operation' group, their Consultant will perform an operation to remove the clot from their brain and closely monitor their condition. If your relative is in the 'non-operation' group, their condition will be closely monitored and they can still receive an operation later, should this become necessary. Whatever group they are allocated to they will receive the best available medical treatment which may include the careful monitoring of pressure inside the skull. In total we hope to recruit 840 patients to this study.

What does my relative have to do?

Once you have indicated that your relative would wish to take part in this study details will be collected from their medical notes regarding the treatment they receive and their response to that treatment. They will have already received a head CT scan before joining the study as part of routine care and they will be given another head CT scan at around 5 days after their treatment has started so that the study research team can analyse the changes after they have received the treatment. Sometimes your relative's 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 receiving treatment your relative and/or you and their carers will be sent postal questionnaires asking how they are managing, about their health generally and about their 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 relative's consultant and/or GP whether they have experienced any complications and where they 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 relative's doctor will be able to discuss these with you. We cannot promise that the study will help your relative, 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 your relative participates in this study their hospital consultant remains in charge of their medical care. If you wish to complain about any aspect of the way they have been approached or treated during the course of this study you should ask to speak to your relative's consultant or the 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 your relative is harmed by taking part in this research project, there are no special compensation arrangements. If they are harmed due to someone's negligence, then they may have grounds for a legal action but they may have to pay for it.

Regardless of this, if you wish to complain formally about any aspect of the way your relative has 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 relative's taking part in this study be kept confidential?

All information collected about your relative 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. We will inform your relative's GP that they are taking part in the study if you do not think they would object to this. 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 your relative as a research participant and nothing that could reveal their 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