INFORMATION SHEET (patient – competent adult)

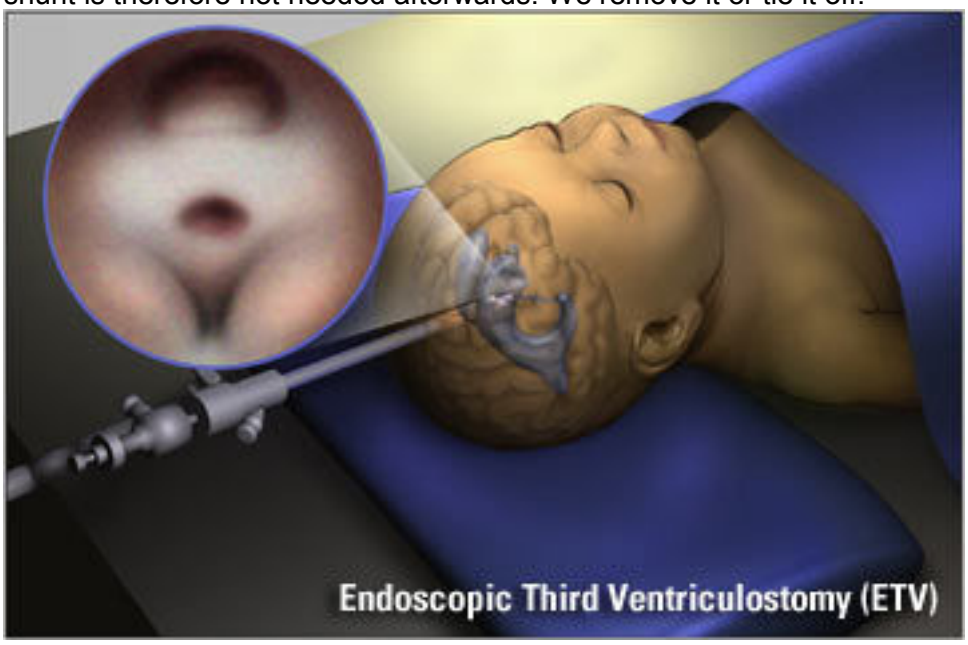
Endoscopic third ventriculostomy versus shunt revision in the treatment of cerebrospinal fluid shunt malfunction

What is the purpose of the study?

People with hydrocephalus (fluid in the brain) are often treated with cerebrospinal fluid (CSF) shunts. These are tubes (with a valve) draining the CSF from the fluid cavities in the brain to the abdomen or the heart or around the lungs. These shunts are prone to blockage, over-drainage or infection. In the case of such shunt malfunction, surgery needs to be carried out to rectify it.

You have been diagnosed with a shunt malfunction. You will need surgery for that. Traditionally we would have replaced part or all of the shunt to treat the problem. You may have had this done before. Unfortunately, the revised shunt is also prone to malfunction and there is a 50:50 chance you would need further surgery within a year.

More recently, we have been able to employ a different procedure to avoid the need for a shunt altogether. This treatment is called an endoscopic third ventriculostomy (ETV). An ETV involves insertion of a thin telescope (an endoscope) into the ventricles of the brain where the CSF is produced. A hole (ventriculostomy) is made in the floor of one of the ventricles (the third ventricle) to allow the CSF to drain out. A shunt is therefore not needed afterwards. We remove it or tie it off.



There is evidence to suggest that an ETV can be as good as or maybe better than shunt revision in people that have a blocked shunt. There is definitely a lower risk of infection than with shunts but there is a slightly higher risk of bleeding from the treatment although this risk is small.

The purpose of this study is to determine whether an ETV or shunt revision is a more effective treatment in people with blocked shunts. In order to eliminate any bias, we need to randomly apply either treatment to patients who have a shunt blockage that need surgery. Overall we need about 450 subjects to reach a valid conclusion and we estimate that the study will take about 5 years.

How does the study work?
Your doctor has told you there is a problem with your shunt and that it isn't working properly. You will need to have surgery to fix this. You're doctor feels that either replacing the shunt or doing an ETV will work.

If you wish to partake in the study, we may perform an MRI scan if one has not been done already. This is to determine if ETV is possible in your case. A pre-sealed envelope will then be opened indicating which treatment will be offered to you. You will then be treated with either a shunt revision or an ETV. Following surgery, we will keep you in for a few days to make sure the treatment has worked. You will be seen about 6 weeks later in the outpatients where further brain imaging will be performed to evaluate the effect of the treatment on the ventricle size.

What other information will be collected in the study?
If you wish to partake in the study, all your clinical details will be recorded by a neurosurgeon. We will also record details of the surgery and how well it went. In 6 weeks you will have a CT scan or an MRI scan to see how big your ventricles are compared to now. At 6 months, 1 year, 2 years and 5 years we will see you again and record details of how you are and whether you've had any symptoms from your hydrocephalus. We'll also record if you've needed further surgery.

Will there be effects on my treatment?
Treatment of your condition will continue on in the routine fashion. Participation will not affect you in any way. Regardless of whether you enter the study or not and regardless of what type of surgery (ETV or shunt revision) you get, we will treat you the same afterwards and during follow-up as an outpatient.

Can I withdraw from the study at any time?
Yes. You are free to refuse to join the study and may withdraw at any time or choose not to answer certain questions. You will receive the same quality of care at the hospital whether you join the study or not.

Will the information obtained in the study be confidential?
All data will be kept in the form of hospital registration numbers. We won't use your name or address. Even then, these hospital numbers can only accessed by the named investigators. Anything you say will be treated in confidence, no names will be mentioned in any reports of the study and care will be taken so that individuals cannot be identified from details in reports of the results of the study.

Will anyone else be told about my participation in the study?
No

What if I wish to complain about the way in which this study has been conducted?
If you have *any* cause to complain about *any* aspect of the way in which you have been approached or treated during the course of this study, the normal National Health Service complaints mechanisms are available to you and are not compromised in any way because you have taken part in a research study.

If you have any complaints or concerns please contact the project coordinator:
Mr. Darach Crimmins,
Leeds General Infirmary
LS1 3EX
(0113) 3928413
darach.crimmins@leedsth.nhs.uk

Otherwise you can use the normal hospital complaints procedure and contact the following person:
Karen Dunwoody
Patient Relations Department,
Ground Floor, Trust Headquarters,
St. James's University Hospital,
Beckett Street,
Leeds LS9 7TF
(0113) 2066261