

Patient agreement to investigation or treatment

Infusion study through a reservoir and proceed to a shunt insertion if needed

Type of shunt.....

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Brief description:

- You have been recommended to have this investigation to assess the problems you are having with hydrocephalus (fluid pressure on the brain). The infusion study is performed to assess if you would benefit from a shunt operation (a tube to drain away fluid). If the test proves that you would benefit from a shunt operation, we would proceed to do this. If the test suggests you would not benefit from a shunt operation, we would not proceed to do this.
- Here, we explain some of the aims, benefits, risks and alternatives to this procedure (operation/treatment). We want you to be informed about your choices to help you to be fully involved in making any decisions.
- Please ask about anything you do not fully understand or wish to have explained in more detail.
- If you would like this information in another format or language or would like help completing the form, please ask a member of our staff.

Please bring this form with you to hospital

- You will be asked to read this form carefully, and you and your doctor (or other appropriate healthcare professional) will sign it to document your consent.
- All our consent forms are available on the Addenbrooke’s website: <http://www.addenbrookes.org.uk/consent>
- Guidance for health professionals can be found on the Addenbrooke’s intranet site <http://nww.addenbrookes.nhs.uk/consent>
- Remember, you can change your mind about having the procedure at any time even after you have signed the form.

For staff use:

Does the patient have any special requirements? (For example: requires an interpreter or other additional communication method)

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About the infusion study

Cerebrospinal fluid (CSF) is produced in the fluid spaces in your brain. It then circulates through these spaces to the spinal canal and back up again to the brain in a loop. Fluid is then reabsorbed in the brain. This cycle normally takes place three times a day. Many things can affect this loop. There may be too much fluid produced. There could be a blockage in part of the loop. Even if the loop is working, it may be inefficient for some reason. Your doctor will discuss this with you.

It is possible to assess how this loop is working by inserting a tube into the fluid spaces in your brain under general anaesthesia. The tube is then connected to a reservoir device. An infusion study involves placing needles into the reservoir and injecting saline fluid (which is made of water and salts). This fluid column is connected to monitoring devices which allow us to make pressure measurements.

If the test proves that a shunt would help you, we would proceed to connect the shunt. A shunt is a tube that the neurosurgeon will tunnel under the skin to drain the fluid to another body cavity. This is usually the abdominal cavity or tummy. It can be another cavity, for example, the spaces around the lungs.

The shunt that will be used is named after the two locations it connects. 'Ventriculo' refers to the fluid spaces in the brain. 'Peritoneal' is the abdominal cavity and 'pleural' is the cavity around the lungs.

Please discuss your type of shunt further with your doctor.

Before your procedure

- You will usually be seen in a pre-admission clinic by a junior doctor and specialist nurse practitioner.
- At this clinic, we shall ask you for details of your medical history and carry out any necessary clinical examinations and investigations. This is a good opportunity for you to ask us any questions about the procedure, but please feel free to discuss any concerns you might have at any time.
- You will be asked if you are taking any tablets or other types of medication - these might be ones prescribed by a doctor or bought over the counter in a pharmacy. It helps us if you bring details with you of anything you are taking (for example: bring the packaging with you).
- Most people who have this type of operation will need to stay in hospital for a few days. Sometimes we can predict whether you will need to stay for longer than usual - your doctor will discuss this with you before you decided to have the operation.

During the procedure itself

- This operation involves the use of general anaesthesia. See page five for further details about anaesthesia.
- The first part of the procedure is the insertion of the tube into the fluid spaces of

the brain. Once this is connected to a reservoir (a reservoir is small plastic bubble which sits under the scalp; it is attached to a tube which sits in the fluid space in the brain and is the size of a 10 pence coin), the infusion study can begin. This will tell us whether to proceed with the shunt operation. You will only proceed with a shunt operation if the study confirms that you would benefit from a shunt. If the study suggests that a shunt is not helpful, we will not proceed. However, we usually leave the tube and the reservoir in place. This tube is blind-ending and not draining any fluid. We do this so that you are able to undergo tests in the future if needed without another operation. This also means you can have a shunt connected easily in the future if one is required.

After the procedure

- You will wake up in the recovery room after your operation. You might have an oxygen mask on your face to help you breathe. You might also wake up feeling sleepy.
- After this procedure, most people will have a small, plastic tube in one of the veins of their arm. This might be attached to a bag of fluid (called a drip), which feeds your body with fluid until you are well enough to eat and drink by yourself.
- While you are in the recovery room, a nurse will check your pulse and blood pressure regularly. When you are well enough to be moved, you will be taken to a ward.
- Sometimes, people feel sick after an operation, especially after a general anaesthetic, and might vomit. If you feel sick, please tell a nurse and you will be offered medicine to make you more comfortable.
- **Eating and drinking:** After this procedure, you should not have anything to eat or drink until your medical team considers it to be safe - this is usually for a few hours.
- **Getting around and about:** After this procedure, we will try to get you mobile (up and about) as soon as we can to help prevent complications from lying in bed. If we think you will have problems getting about, we will arrange for extra assistance, such as nursing help and physiotherapy advice/exercises.
- **When you can leave hospital:** Most people who have had this type of procedure under general anaesthetic are able to leave the hospital in a few days. The actual time that you stay in hospital will depend on your general health, how quickly you recover from the procedure and your doctor's opinion.
- **When you can resume normal activities including work:** Most people who have had this procedure can resume normal activities after a few weeks. You might need to wait a little longer before resuming more vigorous activity. When you will be ready to return to work will depend on your usual health, how fast you recover and what type of work you do. Please ask your doctor for his/her opinion.
- **Special measures you need to take after the procedure:** You will be given more detailed information about any special measures you need to take after the procedure. You will also be given information about things to watch out for that might be early signs of problems (for example, infection).
- **Shunt settings:** If a shunt was inserted, we may need to check the settings before you leave. Please discuss this with your doctor.
- **Check-ups and results:** You will be given an outpatients appointment to be reviewed by the neurosurgeon about three weeks after surgery.

Intended benefits of the procedure

- The aim of the test is to assess whether you have hydrocephalus (fluid pressure on the brain). This condition can be improved with a shunt.

Who will perform my procedure?

- This procedure will be performed by a specialist registrar or consultant neurosurgeon.

Alternative procedures that are available

- For some patients, it is possible to do the infusion study under local anaesthetic. This is done by performing a lumbar puncture. A needle is inserted into the fluid spaces in the spinal canal in the lower back and the infusion study is performed in the usual way. It is not safe to perform a lumbar puncture in certain conditions. Please discuss this with your doctor.
- The alternative to this surgery is to decide not to have surgery. In some patients with hydrocephalus, the fluid pressure can build up and cause serious neuro disability or even death. In patients who have normal pressure hydrocephalus, the fluid pressure is not life-threatening, but surgery can improve symptoms of balance or walking problems, incontinence or memory problems. Please discuss the balance of risks versus benefits with your doctor.

Serious or frequently occurring risks

The risks of any surgical operation:

- **Catastrophe** (1%). Coma or death resulting from the reaction of the brain during surgery. This is rare.
- **Haemorrhage** (5%). Although the risk of bleeding is very small, when it occurs in the brain, it can cause a 'stroke', resulting in permanent neurological disability. This can include limb weakness or paralysis.
- **Respiratory complications** – chest infections which can usually be treated with antibiotics.
- **Blood clots** – there is a risk of deep-vein thrombosis in the legs, which can occasionally pass to the lungs (pulmonary embolism).
- **Wound problems** including wound infection or leakage.
- **Heart**. Problems with your heart, for example, abnormal rhythm or heart attack.
- **Death** (less than 1%).

The risks specifically related to the insertion of a shunt:

- **Shunt malfunction or blockage**. Even though a shunt is positioned correctly, the tube may not drain efficiently, resulting in build-up of fluid pressure again.
- **Shunt infection**. As a shunt tube is a piece of foreign material in the body, it may be necessary to remove the shunt if a serious infection occurs.
- **Subdural haemorrhage**. When the fluid is drained through the shunt, small veins on the surface of the brain may bleed if they are stretched. This problem can be managed with or without further surgery, depending on the severity.

- **Cerebrospinal fluid (CSF) leak.** Fluid may leak through the wound instead of draining through the shunt. This can normally be solved by placing more stitches on the wound. The wound may need to be washed out if the leak is serious.
- **Further surgery.** Usually, patients who have a shunt inserted will need a shunt lifelong. Therefore, further surgery may be required in the future if the shunt is blocked or if a different type is needed.

It is important for you to know that in shunt surgery, having more than one neurosurgical operation does not necessarily reduce your chances of a good outcome.

Information and support

- You might be given some additional patient information before or after the procedure, for example: leaflets that explain what to do after the procedure and what problems to look out for. If you have any questions or anxieties, please feel free to ask a member of staff including Sister Michelle Best, Specialist Nurse Practitioner.

General Anaesthesia

During general anaesthesia you are put into a state of unconsciousness and you will be unaware of anything during the time of your operation. Your anaesthetist achieves this by giving you a combination of drugs.

Before your operation

Before your operation your anaesthetist will visit you in the ward, although occasionally this will happen in a pre-anaesthetic assessment clinic. The anaesthetist who looks after you on the day of your operation is the one who is responsible for making the final decisions about your anaesthetic. He or she will need to understand about your general health, any medication that you are taking and any past health problems that you have had. Your anaesthetist will want to know whether or not you are a smoker, whether you have had any abnormal reactions to any of the drugs or if you have any allergies. They will also want to know about your teeth, whether you wear dentures, have caps or a plate. Your anaesthetist needs to know all these things so that he or she can assess how to look after you in this vital period. Your anaesthetist may examine your heart and lungs and may also prescribe medication that you will be given shortly before your operation, the pre-medication or 'pre-med'.

Pre-medication is the name given to medication (drugs) given to you some hours before your operation. These drugs may be given as tablets, injections or liquids (to children). They relax you and may send you to sleep. They are not always given.

Do not worry if you do not have a pre-med, your anaesthetist has to take many factors into account in making this decision and will take account of your views on the topic if possible. Do not be worried about your anaesthetic. When your anaesthetist visits you before your operation, this is the time to ask all the questions that you may

have, so that you can forget your fears and worries.

Before your operation you will usually be changed into a gown and wheeled to the operating suite into an anaesthetic room. This is an ante-room outside the theatre. The anaesthetist, his or her assistant and nurses are likely to be present. An intravenous line (drip) may be inserted. Monitoring devices may be attached to you, such as a blood pressure cuff or a pulse oximeter. A pulse oximeter is usually a little red light in a small box, which is taped to your finger. It shows how much oxygen you have in your blood and is one of the vital monitors that an anaesthetist uses during your operation to ensure that you remain in the best of health. You may be given some oxygen to breathe. It is common practice nowadays to allow a parent into the anaesthetic room with children: as the child becomes unconscious, the parent will usually be asked to leave.

During your operation

While you are unconscious and unaware your anaesthetist remains with you at all times. He or she monitors your condition and administers the right amount of anaesthetic drugs to maintain you in the correct level of unconsciousness for the period of the surgery. Your anaesthetist is constantly aware of your condition and trained to respond. Your anaesthetist will be monitoring such factors as your heart rate, blood pressure, heart rhythm, body temperature and breathing. He or she will also constantly watch your need for fluid or blood replacement. If you have any other medical conditions, your anaesthetist will know of these from your pre-operative assessment and be able to treat them during surgery.

After your operation

After your operation your anaesthetist continues to monitor your condition carefully. You will probably be transferred to a recovery ward where specially trained nurses, under the direction of anaesthetists, will look after you. Your anaesthetist and the recovery nurses will ensure that all the anaesthetic effects are reversed and that you are closely monitored as you return to full consciousness. You may be given some oxygen to breathe in the recovery area, and may find that intravenous drips have been inserted whilst you are unconscious in theatre and that these will be replacing fluids that you might require. You will be given medication for any pain that you might feel, and systems, such as Patient Controlled Analgesia (PCA) may be set up to continue pain control on the ward.

You are likely to feel drowsy and sleepy at this stage. Some patients feel sick, others may have a sore throat related to the insertion of the breathing tube during surgery. During this time it is important that you relax as much as you can, breathe deeply, do not be afraid to cough, and do not hesitate to ask the nursing staff for any pain relief, and about any queries you may have. You are likely to have hazy memories of this time and some patients experience vivid dreams. Once you are fully awake you will be returned to the ward, and if you are a day patient will be allowed to go to the waiting area to fully recover before you are accompanied home. Do not expect to feel

completely normal immediately!

What are the risks of general anaesthesia?

In modern anaesthesia, serious problems are uncommon. Risks cannot be removed completely, but modern equipment, training and drugs have made it a much safer procedure in recent years. The risk to you as an individual will depend on whether you have any other illness, personal factors (such as smoking or being overweight) or surgery which is complicated, long or done in an emergency. Please discuss any pre-existing medical condition with your anaesthetist.

- Very common and common side effects (1 in 10 or 1 in 100 people)
Feeling sick and vomiting after surgery, sore throat, dizziness, blurred vision, headache, itching, aches, pains and backache, pain during injection of drugs, bruising and soreness, confusion or memory loss.
- Uncommon side effects and complications (1 in 1000 people)
Chest infection, bladder problems, muscle pains, slow breathing (depressed respiration), damage to teeth, lips or tongue, an existing medical condition getting worse, awareness (becoming conscious during your operation).
- Rare or very rare complications (1 in 10,000 or 1 in 100,000)
Damage to the eyes, serious allergy to drugs, nerve damage, death, equipment failure.



Addenbrooke's is smoke-free. You cannot smoke on site. For advice on quitting, contact your GP or the NHS smoking helpline free, 0800 169 0 169

Please ask if you require this information in other languages, large print or audio format: 01223 216032 or patient.information@addenbrookes.nhs.uk

Informacje te można otrzymać w innych językach, w wersji dużym drukiem lub audio. Zamówienia prosimy składać pod numerem: 01223 216032 lub wysyłając e-mail: patient.information@addenbrookes.nhs.uk

Polish

Se precisar desta informação num outro idioma, em impressão de letras grandes ou formato áudio por favor telefone para o 01223 216032 ou envie uma mensagem para: patient.information@addenbrookes.nhs.uk

Portuguese

Если вам требуется эта информация на другом языке, крупным шрифтом или в аудиоформате, пожалуйста, обращайтесь по телефону 01223 216032 или на вебсайт patient.information@addenbrookes.nhs.uk

Russian

若你需要此信息的其他語言版本、大字體版或音頻格式，請致電 01223 216032 或發郵件到: patient.information@addenbrookes.nhs.uk

Cantonese

Bu bilgiyi diger dillerde veya büyük baskılı ya da sesli formatta isterseniz lütfen su numaradan kontak kurun: 01223 216032 veya asagidaki adrese e-posta gönderin: patient.information@addenbrookes.nhs.uk

Turkish

এই তথ্য বাংলায়, বড় অক্ষরে বা অডিও টেপে পেতে চাইলে দয়া করে 01223 216032 নম্বরে ফোন করুন বা patient.information@addenbrookes.nhs.uk ঠিকানায় ই-মেইল করুন।

Bengali

Document History

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Consent form 1

For staff use only:
Surname:
First names:
Date of birth:
Hospital no:
Male/Female:
(Use hospital identification label)

Patient agreement to investigation or treatment

Responsible health professional/job title

Special requirements
 (For example, other language/other communication method)

Name of proposed procedure or course of treatment

Infusion study through a reservoir and proceed to a shunt insertion if needed. Type of shunt..... Side (left/right)

Statement of health professional

(To be filled in by a health professional with an **appropriate knowledge of the proposed procedure**, as specified in the Hospital's consent policy)

I have explained the procedure to the patient. In particular, I have explained:

- The intended benefits of the procedure : to assess whether you have hydrocephalus (fluid pressure on the brain). This condition can be improved with a shunt.
- Any serious or frequently occurring risks from the procedures including those specific to the patient: **The risks of any surgical operation:** Coma or death resulting from the reaction of the brain during surgery (1%). This is rare; Haemorrhage (5%) (which can cause a 'stroke', resulting in permanent neurological disability. This can include limb weakness or paralysis); respiratory complications; blood clots – there is a risk of deep-vein thrombosis in the legs, which can occasionally pass to the lungs (pulmonary embolism); wound problems including wound infection or leakage; problems with your heart for example, abnormal rhythm or heart attack; death (less than 1%). **The risks specifically related to the insertion of a shunt:** shunt malfunction or blockage; the tube may not drain efficiently, resulting in build-up of fluid pressure again; shunt infection. it may be necessary to remove the shunt if a serious infection occurs; subdural haemorrhage; cerebrospinal fluid (CSF) leak; further surgery.
 Other (please specify)

• Any extra procedures that might become necessary during the procedure:

Blood transfusion Other procedure (please specify)

I have discussed what the treatment / procedure is likely to involve, the benefits and risks of any available alternative treatments (including no treatment) and any particular concerns of this patient.

- The following information leaflet has been provided: Infusion study through a reservoir and proceed to a shunt insertion if needed. Version/Date/Ref: CF395, version 1 January 2009

This procedure will involve:

General and/or regional anaesthesia Local anaesthesia Sedation

Health professional's signature:Date:

Name (PRINT): Job title:

Contact details (if patient wishes to discuss details later)

I have offered the patient information about the procedure but s/he has declined information.

Statement of the interpreter (if appropriate)

I have interpreted the information to the best of my ability, and in a way in which I believe s/he can understand:

Interpreter's signature..... Date:

Name (PRINT):

Important notes: (tick if applicable)

- The patient has withdrawn consent (ask patient to sign/date here)
- See also advance directive/living will

Copy accepted by patient: yes / no (please circle)

<p>For staff use only: Surname: First names: Date of birth: Hospital no: Male/Female: (Use hospital identification label)</p>
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Statement of patient

Please read this form carefully. If your treatment has been planned in advance, you should already have your own copy, which describes the benefits and risks of the proposed treatment. If not, you will be offered a copy now. Do ask if you have any further questions. The staff at Addenbrooke's are here to help you. **You have the right to change your mind at any time before the procedure is undertaken, including after you have signed this form.**

Training doctors and other health professionals is essential to the continuation of the Health Service and improving the quality of care. Your treatment may provide an important opportunity for such training, where necessary under the careful supervision of a senior doctor. You may, however, decline to be involved in the formal training of medical and other students without this adversely affecting your care and treatment.

Please read the following:

I understand that I will have the opportunity to discuss the details of anaesthesia with an anaesthetist before the procedure, unless the urgency of my situation prevents this. (This only applies to patients having general or regional anaesthesia.)

I understand that you cannot give me a guarantee that a particular person will perform the procedure. The person undertaking the procedure will, however, have appropriate experience.

I understand that any procedure in addition to those described on this form will only be carried out if it is necessary to save my life or to prevent serious harm to my health.

I have been told about additional procedures which may become necessary during my treatment. I have listed below any procedures that **I do not wish, without further discussion, to be carried out.**

I understand that any tissue (including blood) removed as part of the procedure or treatment will be anonymised and may be used for teaching or quality control, and stored or disposed of in a manner regulated by appropriate, ethical, legal and professional standards.

I understand that all research will be approved by a research ethics committee and undertaken in accordance with appropriate ethical, legal and professional standards.

I understand that the research may be conducted within a hospital, university, not for profit organisation or a company laboratory.

Please tick boxes to indicate you either agree/disagree to the three points below. Yes No

I agree that tissue (including blood) not needed for my own diagnosis or treatment can be used for **research which may include genetic research.** **If you wish** to withdraw your consent for the use of your tissue (including blood) for research, please contact the Patient Advice and Liaison Service at Addenbrooke's Hospital.

I agree to the use of photography for the purpose of diagnosis and treatment.

I agree to anonymised photographs being used for medical teaching.

I confirm that the risks, benefits and alternatives of this procedure have been discussed with me and I have read and understood the above and agree to the procedure (or course of treatment) on this form.

Patient's signature:..... **Date:**

Name (PRINT):

If the patient is unable to sign but has indicated his/her consent, a witness should sign below. Young people may also like a parent to sign here (see guidance notes).

Witness' signature: **Date:**

Name (PRINT):

Confirmation of consent (to be completed by a health professional when the patient is admitted for the procedure, if the patient has signed the form in advance)

On behalf of the team treating the patient, I have confirmed with the patient that s/he has no further questions and wishes the procedure to go ahead.

Signature Date:

Name (PRINT): Job Title: