Patient information and consent to low flow extracranial to intracranial bypass (STA-MCA) surgery to reduce the chances of future strokes

Key messages for patients

- Please read your admission letter carefully. It is important to follow the instructions we give you about not eating or drinking or we may have to postpone or cancel your operation.

- Please read this information carefully, you and your health professional will sign it to document your consent.

- It is important that you bring the consent form with you when you are admitted for surgery. You will have an opportunity to ask any questions from the surgeon or anaesthetist when you are admitted. You may sign the consent form either before you come or when you are admitted.

- Please bring with you all of your medications and its packaging (including inhalers, injections, creams, eye drops, patches, insulin and herbal remedies), a current repeat prescription from your GP, any cards about your treatment and any information that you have been given relevant to your care in hospital, such as x rays or test results.

- Laxatives and painkillers may be required after your hospital stay; please ensure you have appropriate supplies at home.

- Take your medications as normal on the day of the procedure unless you have been specifically told not to take a drug or drugs before or on the day by a member of your medical team. If you have diabetes please ask for specific individual advice to be given on your medication at your pre-operative assessment appointment.

- Please call the Neurovascular Clinical Nurse Specialist (CNS) on telephone number 01223 256981 if you have any questions or concerns about this procedure or your appointment.

After the procedure we will file the consent form in your medical notes and you may take this information leaflet home with you.

Important things you need to know

Patient choice is an important part of your care. You have the right to change your mind at any time, even after you have given consent and the procedure has started (as long as it is safe and practical to do so). If you are having an anaesthetic you will have the opportunity to discuss this with the anaesthetist, unless the urgency of your treatment prevents this.

We will also only carry out the procedure on your consent form unless, in the opinion of the responsible health professional responsible for your care, a further procedure is needed in order to save your life or prevent serious harm to your health. However, there may be procedures you do not wish us to carry out and these can be recorded on the consent form. We are unable to guarantee that a particular person will perform the procedure. However the person undertaking the procedure will have the relevant experience.

All information we hold about you is stored according to the Data Protection Act 1998.

CF381, Version 4, September 2017
About low flow extracranial to intracranial bypass (STA-MCA) surgery to reduce the chances of future strokes

- An extracranial to intracranial bypass operation is where a blood vessel is used to provide an additional blood supply to cerebral circulation.
- The reason for carrying out such an operation is to improve the blood flow to the brain and reduce the chances of stroke occurring.
- Your preoperative investigations would have demonstrated that the blood flow to the brain is low, and this is the likely cause of your symptoms.
- With successful surgery the risks of stroke can be reduced significantly, and many patients will notice an improvement in their symptoms.
- Please ask about anything you do not fully understand or wish to have explained in more detail.

**Intended benefits**
To improve the blood flow to the brain and reduce the chances of stroke occurring.

**Who will perform my procedure?**
This procedure will be performed by the Consultant Neurosurgeon with the assistance of a Specialist Registrar.

**Before your procedure**
Most patients attend a pre-admission clinic, when you will meet a member of the neurosurgical team. At this clinic, we will ask for details of your medical history and carry out any necessary clinical examinations and investigations. Please ask us any questions about the procedure, and feel free to discuss any concerns you might have at any time.

We will ask if you take any tablets or use any other types of medication either prescribed by a doctor or bought over the counter in a pharmacy. Please bring all your medications and any packaging (if available) with you. Please tell the ward staff about all of the medicines you use. If you wish to take your medication yourself (self-medicate), please ask your nurse. Pharmacists visit the wards regularly and can help with any medicine queries.

This procedure involves the use of general anaesthesia. We explain about the different types of anaesthesia or sedation we may use at the end of this leaflet. You will see an anaesthetist before your procedure.

Most people who have this type of procedure will need to stay in hospital for three to five days. Sometimes we can predict whether you will need to stay for longer than usual - your doctor will discuss this with you before you decide to have the procedure.

**Medication:** **You need to continue taking your medications as normal including aspirin. If you are prescribed Clopidogrel (or Plavix) please stop taking this one week before your operation and this may be changed to aspirin.**
If you are on any major anti coagulant medication such as Warfarin, this will need to be stopped before surgery after discussion with your surgeons.

During surgery, you may lose blood. If you lose a considerable amount of blood your doctor may want to replace the loss with a blood transfusion as significant blood loss can cause you harm. The blood transfusion can involve giving you other blood components such as plasma and platelets which are necessary for blood clotting. Your doctor will only give you a transfusion of blood or blood components during surgery, or recommend for you to have a transfusion after surgery, if you need it.

Compared to other everyday risks the likelihood of getting a serious side effect from a transfusion of blood or blood component is very low. Your doctor can explain to you the benefits and risks from a blood transfusion. Your doctor can also give you information about whether there are suitable alternatives to blood transfusion for your treatment. There is a patient information leaflet for blood transfusion available for you to read.

**During the procedure**

- If you have a general anaesthetic, you will be kept asleep until you reach the recovery room after the procedure.

**After the procedure**

Once your surgery is completed you will usually be transferred to the recovery ward where you will be looked after by specially trained nurses, under the direction of your anaesthetist. The nurses will monitor you closely until the effects of any general anaesthetic have adequately worn off and you are conscious. They will monitor your heart rate, blood pressure and oxygen levels too. You may be given oxygen via a facemask, fluids via your drip and appropriate pain relief until you are comfortable enough to return to your ward. When you first wake up, there might be a small probe attached to the side of your head with an elasticated band. This probe monitors the blood supply to the brain, which ensures that the repaired artery remains clear. You may also find there is a urinary catheter inserted into your bladder, which allows your urine to drain into a bag. This is a temporary measure to prevent urine becoming retained which can cause your blood pressure to become unstable.

After a few hours, if all the measurements are fine and you have recovered sufficiently from the anaesthetic, you will be returned to the ward where you will continue to be monitored closely for 24 hours (neurological observations will be one to two hourly overnight). Alternatively, we may continue to monitor you within the high dependency area overnight.

If there is not a bed in the necessary unit on the day of your operation, your operation may be postponed as it is important that you have the correct level of care after major surgery.
Eating and drinking. The day after the operation, if all is well, you are allowed to start to eat and drink.

Getting about after the procedure. The day after the operation, if all is well, the monitors, catheters and drains are removed. We will help you to become mobile as soon as possible after the procedure. This helps improve your recovery and reduces the risk of certain complications. If you have any mobility problems, we can arrange nursing or physiotherapy help.

Leaving hospital. While you are staying with us, the surgical team will visit you every day and can answer any questions you might have about your surgery. On each visit, we will assess your progress and work out the best time for you to be discharged from hospital. Most people are discharged two to three days after the operation. However, the actual time that you stay in hospital will depend on your general health, how quickly you are recovering from the procedure and your doctor's opinion.

Resuming normal activities including work. You will probably need two to four weeks off work or study; please return when you feel comfortable. You should avoid driving for at least two to four weeks ie, until you regain the full range of pain-free movement in your neck. Gentle exercise (for example, walking) is good but avoid any heavy lifting or straining until fully recovered. You may resume sex after two to four weeks.

Special measures after the procedure:
Ultra sound: this will be performed the day after surgery to check the patency of the graft. 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).

Important: You must avoid compression over the graft site – nasal specs will be used instead of an oxygen mask. Glasses must not be worn unless the arm of the glasses is removed on the same side as the graft site. We can review this when we see you in clinic two to three months post operatively.

Check-ups and results: We will make arrangements to review you in the outpatient clinic three months after the operation. We will perform an ultrasound scan of the operated artery. If all is well, you can be discharged back to the care of your GP.
Significant, unavoidable or frequently occurring risks of this procedure

- There is a small risk of stroke at the time of operation (approximately 2 to 3%). To keep this risk as low as possible, we monitor your brain function throughout the surgery with a variety of techniques. We also thin the blood using heparin during surgery, and give you aspirin which reduces the ‘stickiness’ of the platelets in the blood.

- All major operations carry general risks including problems with the heart. On average there is a 1 to 2% risk of a heart attack following surgery. Often, this is related to problems with unstable blood pressure in the first 24 hours following surgery. For this reason, we monitor your blood pressure very carefully during this period, and give medications to prevent your blood pressure becoming too high or too low.

- The surgery will be in the region of the temporal part of your head in front of the ear. After surgery there may be some swelling and bruising and a feeling of tightness. This is normal. Because you are taking aspirin, and because we administer heparin during the operation, a substantial swelling under the skin can occasionally occur. Normally we do not need to treat this, but on occasions you may return to theatre to have a collection of blood removed.

Alternative procedures that are available

You will already be on maximum medical therapy prior to your surgery. There are currently no alternative treatments to reduce your risk of stroke.

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 the Clinical Nurse Practitioner who can be contacted via the Addenbrooke’s switchboard on 01223 245151 and asking them to bleep 152-165.

Anaesthesia

Anaesthesia means ‘loss of sensation’. There are three types of anaesthesia: general, regional and local. The type of anaesthesia chosen by your anaesthetist depends on the nature of your surgery as well as your health and fitness. Sometimes different types of anaesthesia are used together.

Before your operation

Before your operation you will meet an anaesthetist who will discuss with you the most appropriate type of anaesthetic for your operation, and pain relief after your surgery.
To inform this decision, he/she will need to know about:

- your general health, including previous and current health problems
- whether you or anyone in your family has had problems with anaesthetics
- any medicines or drugs you use
- whether you smoke
- whether you have had any abnormal reactions to any drugs or have any other allergies
- your teeth, whether you wear dentures, or have caps or crowns.

Your anaesthetist may need to listen to your heart and lungs, ask you to open your mouth and move your neck and will review your test results.

**Pre-medication**

You may be prescribed a ‘premed’ prior to your operation. This is a drug or combination of drugs which may be used to make you sleepy and relaxed before surgery, provide pain relief, reduce the risk of you being sick, or have effects specific for the procedure that you are going to have or for any medical conditions that you may have. *Not all patients will be given a premed or will require one and the anaesthetist will often use drugs in the operating theatre to produce the same effects.*

**Moving to the operating room or theatre**

You will usually change into a gown before your operation and we will take you to the operating suite. When you arrive in the theatre or anaesthetic room and before starting your anaesthesia, the medical team will perform a check of your name, personal details and confirm the operation you are expecting.

Once that is complete, monitoring devices may be attached to you, such as a blood pressure cuff, heart monitor (ECG) and a monitor to check your oxygen levels (a pulse oximeter). An intravenous line (drip) may be inserted. If a regional anaesthetic is going to be performed, this may be performed at this stage. If you are to have a general anaesthetic, you may be asked to breathe oxygen through a face mask.

It is common practice nowadays to allow a parent into the anaesthetic room with children; as the child goes unconscious, the parent will be asked to leave.

**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.

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 at the correct level of unconsciousness for the period of the surgery. Your anaesthetist will be monitoring such factors as heart rate, blood pressure, heart rhythm, body temperature and breathing. He or she will also constantly watch your need for fluid or blood replacement.
Regional anaesthesia

Regional anaesthesia includes epidurals, spinals, caudals or local anaesthetic blocks of the nerves to the limbs or other areas of the body. Local anaesthetic is injected near to nerves, numbing the relevant area and possibly making the affected part of the body difficult or impossible to move for a period of time. Regional anaesthesia may be performed as the sole anaesthetic for your operation, with or without sedation, or with a general anaesthetic. Regional anaesthesia may also be used to provide pain relief after your surgery for hours or even days. Your anaesthetist will discuss the procedure, benefits and risks with you and, if you are to have a general anaesthetic as well, whether the regional anaesthesia will be performed before you are given the general anaesthetic.

Local anaesthesia

In local anaesthesia the local anaesthetic drug is injected into the skin and tissues at the site of the operation. The area of numbness will be restricted. Some sensation of pressure may be present, but there should be no pain. Local anaesthesia is used for minor operations such as stitching a cut, but may also be injected around the surgical site to help with pain relief. Usually a local anaesthetic will be given by the doctor doing the operation.

Sedation

Sedation is the use of small amounts of anaesthetic or similar drugs to produce a ‘sleepy-like’ state. Sedation may be used as well as a local or regional anaesthetic. The anaesthesia prevents you from feeling pain and the sedation makes you drowsy. Sedation also makes you physically and mentally relaxed during an investigation or procedure which may be unpleasant or painful (such as an endoscopy) but where your co-operation is needed. You may remember a little about what happened but often you will remember nothing. Sedation may be used by other professionals as well as anaesthetists.

What will I feel like afterwards?

How you will feel will depend on the type of anaesthetic and operation you have had, how much pain relieving medicine you need and your general health.

Most people will feel fine after their operation. Some people may feel dizzy, sick or have general aches and pains. Others may experience some blurred vision, drowsiness, a sore throat, headache or breathing difficulties.

You may have fewer of these effects after local or regional anaesthesia although when the effects of the anaesthesia wear off you may need pain relieving medicines.
What are the risks of 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 performed in an emergency.

**Very common (1 in 10 people) and common side effects (1 in 100 people)**
- Feeling sick and vomiting after surgery
- Sore throat
- Dizziness, blurred vision
- Headache
- Bladder problems
- Damage to lips or tongue (usually minor)
- 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
- Muscle pains
- Slow breathing (depressed respiration)
- Damage to teeth
- An existing medical condition getting worse
- Awareness (becoming conscious during your operation)

**Rare (1 in 10,000 people) and very rare (1 in 100,000 people) complications**
- Damage to the eyes
- Heart attack or stroke
- Serious allergy to drugs
- Nerve damage
- Death
- Equipment failure

Deaths caused by anaesthesia are very rare. There are probably about five deaths for every million anaesthetics in the UK.

For more information about anaesthesia, please visit the Royal College of Anaesthetists’ website: [www.rcoa.ac.uk](http://www.rcoa.ac.uk)
Information about important questions on the consent form

1 Creutzfeldt Jakob Disease (‘CJD’)
We must take special measures with hospital instruments if there is a possibility you have been at risk of CJD or variant CJD disease. We therefore ask all patients undergoing any surgical procedure if they have been told that they are at increased risk of either of these forms of CJD. This helps prevent the spread of CJD to the wider public. A positive answer will not stop your procedure taking place, but enables us to plan your operation to minimise any risk of transmission to other patients.

2 Photography, Audio or Visual Recordings
As a leading teaching hospital we take great pride in our research and staff training. We ask for your permission to use images and recordings for your diagnosis and treatment; they will form part of your medical record. We also ask for your permission to use these images for audit and in training medical and other healthcare staff and UK medical students; you do not have to agree and if you prefer not to, this will not affect the care and treatment we provide. We will ask for your separate written permission to use any images or recordings in publications or research.

3 Students in training
Training doctors and other health professionals is essential to the NHS. Your treatment may provide an important opportunity for such training, where necessary under the careful supervision of a registered professional. You may, however, prefer not to take part in the formal training of medical and other students without this affecting your care and treatment.

4 Use of Tissue
As a leading biomedical research centre and teaching hospital, we may be able to use tissue not needed for your treatment or diagnosis to carry out research, for quality control or to train medical staff for the future. Any such research, or storage or disposal of tissue, will be carried out in accordance with ethical, legal and professional standards. In order to carry out such research we need your consent. Any research will only be carried out if it has received ethical approval from a Research Ethics Committee. You do not have to agree and if you prefer not to, this will not in any way affect the care and treatment we provide. The leaflet ‘Donating tissue or cells for research’ gives more detailed information. Please ask for a copy.

If you wish to withdraw your consent on the use of tissue (including blood) for research, please contact our Patient Advice and Liaison Service (PALS), on 01223 216756.
Privacy & dignity

Same sex bays and bathrooms are offered in all wards except critical care and theatre recovery areas where the use of high-tech equipment and/or specialist one to one care is required.

We are now a smoke-free site: smoking will not be allowed anywhere on the hospital site. For advice and support in quitting, contact your GP or the free NHS stop smoking helpline on 0800 169 0 169.

Other formats:

If you would like this information in another language, large print or audio, please ask the department where you are being treated, to contact the patient information team: patient.info@addenbrookes.nhs.uk.

Please note: We do not currently hold many leaflets in other languages; written translation requests are funded and agreed by the department who has authored the leaflet.

Document history

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Consent Form

Patient agreement to investigation or treatment for neurosurgery, spinal surgery or vitreoretinal surgery

Please use ‘Procedure completed’ stamp below on completion:

Interpreter’s statement (if appropriate)

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

Signed (Interpreter): ..................................................  Date: ........................................

Name (PRINT): ..............................................................

Or, please note the language line reference ID number:

Patient safety – at the heart of all we do

Addenbrooke’s Hospital | Rosie Hospital

File: in the procedures and consents section of the casenotes
Low flow Extracranial to intracranial bypass (STA-MCA) surgery

To improve the blood flow to the brain and reduce the chances of stroke occurring.

Small risk of stroke at the time of operation, all major operations carries general risks including problems with the heart. After surgery there may be some swelling and bruising and a feeling of tightness.

c) what the treatment or procedure is likely to involve, the benefits and risks of any available alternative treatments (including no treatment) and any particular concerns of this patient:

d) any extra procedures that might become necessary during the procedure such as:
   - Blood transfusion
   - Other procedure (please state)

e) Was the patient born after 1 January 1997?
   - Yes
   - No

The following information leaflet has been provided:
Low flow extracranial to intracranial bypass (STA-MCA) surgery
Version reference and date: CF381 version 4 September 2017

or I have offered the patient information about the procedure but this has been declined.

This procedure will involve:
- General and/or regional anaesthesia
- Local anaesthesia
- Sedation
- None

Signed (Health professional):

Date: D M M Y Y Y

Name (PRINT):

Time (24hr):

Designation:

Contact/bleep no:
**Consent of patient/person with parental responsibility**

I **confirm** that the risks, benefits and alternatives of this procedure have been discussed with me and that my questions have been answered to my satisfaction and understanding.

**Important:** please read the patient information on ‘Consent’ and then put a tick in the relevant boxes for the following questions:

1. **Creutzfeldt Jakob disease (CJD)**
   - **a)** Have you ever been notified that you are at risk of CJD or variant CJD for public health purposes? If yes, please inform your health professional.  
     - Yes  
     - No
   
   **b)** Have you had a history of CJD or other prion disease in your family?  
     - Yes  
     - No
   
   **c)** Have you ever received growth hormone or gonadotrophin treatment?  
     - Yes  
     - No
     *If yes, please give details below:*
     
     Please specify:
     - (i) whether the hormone was derived from human pituitary glands  
       - Yes  
       - No
     - (ii) the year of treatment
     - (iii) whether the treatment was received in the UK or another country  
       - UK  
       - Other
   
   **d)** Have you ever had surgery on your brain, eye or spinal cord?  
     - Yes  
     - No
     *If yes, please give details below:

   e) Since 1980, have you had any transfusions of blood or blood components (red cells, plasma, cryoprecipitate or platelets)?  
    - Yes  
    - No
    *If yes, please answer questions below:*

    Have you either:
    - (i) received more than 50 units of blood or blood components,  
      - Yes  
      - No
    - or
    - (ii) received blood or blood components on more than 20 occasions  
      - Yes  
      - No

    Where possible, please provide the names of all the hospitals where you received blood or blood components:

**In the case of a positive reply to any CJD question, staff should immediately inform Infection Control on ext 3497 (bleep numbers 152-198 or 151-803) and the theatre co-ordinator (24 hour bleep number 152-585); out of hours contact the on call medical microbiologist via the hospital contact centre.**

2. **Photography, Audio or Visual Recording**
   - **a)** I **agree** to the use of any of the above type of recordings for the purpose of diagnosis and treatment.  
     - Yes  
     - No
   
   **b)** I **agree** to unidentified versions of any of the above recordings being used for audit and medical teaching in a healthcare setting.  
     - Yes  
     - No

3. **Medical Training**
   - I **agree** to the involvement of medical and other students as part of their formal training.  
     - Yes  
     - No
Use of Tissue

a) I agree that tissue (including blood) not needed for my own diagnosis or treatment can be used and stored for ethically approved research which may include ethically approved genetic research. □ Yes   □ No

b) Where additional clinical information is needed for the purposes of ethically approved research, I agree that relevant sections of my medical record may be looked at by researchers or by relevant regulatory authorities. I give permission for these individuals to have access to my records. □ Yes   □ No

I have listed below any procedures that I do not wish to be carried out without further discussion.

I have read and understood the Patient Information entitled Consent and the above additional information. I agree to the procedure or treatment.

Signed (Patient): __________________________ Date: ____________

Name of patient (PRINT): __________________________

If signing for a child or young person; delete if not applicable.
I confirm I am a person with parental responsibility for the patient named on this form.

Signed: __________________________ Date: ____________

Relationship to patient: __________________________

If the patient is unable to sign but has indicated his/her consent, a witness should sign below.

Signed (Witness): __________________________ Date: ____________

Name of witness (PRINT): __________________________

Address: __________________________

D Confirmation of consent

Confirmation of consent (where the treatment/procedure has been discussed in advance)
On behalf of the team treating the patient, I have confirmed with the patient that she/he has no further questions and wishes the treatment/procedure to go ahead.

Signed (Health professional): __________________________ Date: ____________

Name (PRINT): __________________________ Job title: __________________________

Please initial to confirm all sections have been completed: __________________________

E Withdrawal of patient consent

□ The patient has withdrawn consent (ask patient to sign and date here)

Signed (Patient): __________________________ Date: ____________

Signed (Health professional): __________________________ Date: ____________

Name (PRINT): __________________________ Job title: __________________________