



Queensland
Government

Cerebral Vasospasm Treatment Consent

Adult (18 years and over)

Facility:

(Affix identification label here)

URN:

Family name:

Given name(s):

Address:

Date of birth:

Sex: M F I

A. Does the patient have capacity to provide consent?

- Yes → **GO TO section B**
 No → **COMPLETE section A**

You must adhere to the Advance Health Directive (AHD), or if there is no AHD, the consent obtained from a substitute decision-maker in the following order: Category 1. Tribunal-appointed guardian; 2. Enduring Power of Attorney; or 3. Statutory Health Attorney.

Name of substitute decision-maker:

Category of substitute decision-maker:

B. Is an interpreter required?

- Yes No

If yes, the interpreter has:

- provided a sight translation of the informed consent form in person
 translated the informed consent form over the telephone

It is acknowledged that a verbal translation is usually a summary of the text on the form, rather than word-by-word translation.

Name of interpreter:

Interpreter code:

Language:

C. Patient/substitute decision-maker confirms the following procedure(s)

I confirm that the referring doctor/clinician has explained that I have been referred for the following procedure:

- Cerebral vasospasm treatment: Yes No
 Medication
 Angioplasty

Site/side of treatment:

Name of referring doctor/clinician:

D. Risks specific to the patient in having a cerebral vasospasm treatment

(Doctor/clinician to document additional risks not included in the patient information sheet):

E. Risks specific to the patient in *not* having a cerebral vasospasm treatment

(Doctor/clinician to document specific risks in not having a cerebral vasospasm treatment):

F. Alternative procedure options

(Doctor/clinician to document alternative procedure not included in the patient information sheet):

G. Information for the doctor/clinician

The information in this consent form is not intended to be a substitute for direct communication between the doctor/clinician and the patient/substitute decision-maker.

I have explained to the patient/substitute decision-maker the contents of this form and am of the opinion that the information has been understood.

Name of doctor/clinician:

Designation:

Signature:

Date:

DO NOT WRITE IN THIS BINDING MARGIN

v1.00
Clinical content review: 2023
Clinical check: 10/2023
Published: 10/2023



SW9623

CEREBRAL VASOSPASM TREATMENT CONSENT



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Adult (18 years and over)

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H. Patient/substitute decision-maker consent

I acknowledge that the doctor/clinician has explained:

- the 'Cerebral Vasospasm Treatment' patient information sheet
- the medical condition and proposed treatment, including the possibility of additional treatment
- the specific risks and benefits of the treatment
- the prognosis, and risks of not having the treatment
- alternative treatment options
- that there is no guarantee the treatment will improve the medical condition
- that if a life-threatening event occurs during the treatment, I will be treated based on documented discussions (e.g. AHD or ARP [Acute Resuscitation Plan])
- that a doctor/clinician other than the consultant/specialist may assist with/conduct the clinically appropriate treatment; this may include a doctor/clinician undergoing further training under supervision
- that if the doctor/clinician wishes to record video, audio or images during the procedure where the recording is not required as part of the treatment (e.g. for training or research purposes), I will be asked to sign a separate consent form. If I choose not to consent, it will not adversely affect my access, outcome or rights to medical treatment in any way.

I was able to ask questions and raise concerns with the doctor/clinician.

I understand I have the right to change my mind regarding consent at any time, including after signing this form (*this should be in consultation with the doctor/clinician*).

I/substitute decision-maker have received the following consent and patient information sheet(s):

- 'Cerebral Vasospasm Treatment'
- 'About Your Anaesthetic'

On the basis of the above statements,

1) I/substitute decision-maker consent to having a cerebral vasospasm treatment.

Name of patient/substitute decision-maker:

Signature:

Date:

2) Student examination/procedure for professional training purposes:

For the purpose of undertaking training, a clinical student(s) may observe medical examination(s) or procedure(s) and may also, subject to patient/substitute decision-maker consent, assist with/conduct an examination or procedure on a patient while the patient is under anaesthetic.

I/substitute decision-maker consent to a clinical student(s) undergoing training to:

- observe examination(s)/procedure(s) Yes No
- assist with examination(s)/procedure(s) Yes No
- conduct examination(s)/procedure(s) Yes No

Cerebral Vasospasm Treatment

Adult (18 years and over) | Informed consent: patient information

A copy of this patient information sheet should be given to the patient or substitute decision-maker to read carefully and allow time to ask any questions about the procedure. The consent form and patient information sheet should be included in the patient's medical record.

In this information sheet, the word 'you' means the patient unless a substitute decision-maker is providing consent on behalf of the patient, in which case the word 'you' means the substitute decision-maker when used in the context of the person providing consent to the treatment.



1. What is a cerebral vasospasm treatment and how will it help me?

Cerebral vasospasm is the sudden narrowing of a blood vessel which leads to a decrease of blood flow to the brain. If left untreated it can result in a stroke.

Treatment for cerebral vasospasm includes injecting medication directly into the narrowed blood vessels. This medication may help to open up the blood vessels. Repeated cerebral injections may be required until the vasospasm settles. Sometimes an

angioplasty may be considered, this is where a special balloon is inflated into the narrowed blood vessel to help open it up and improve the blood flow.

Your doctor/clinician will choose the best treatment method suited to your condition.

Cerebral vasospasm treatment is performed as an extra step to a cerebral angiogram procedure. An angiogram is a procedure where x-rays and iodinated contrast (also known as x-ray dye) are used to examine the blood flow in your brain and to locate the vessels that are in vasospasm. An angiogram is done by placing a needle and a thin plastic tube (catheter) into an artery either in your groin or your arm.

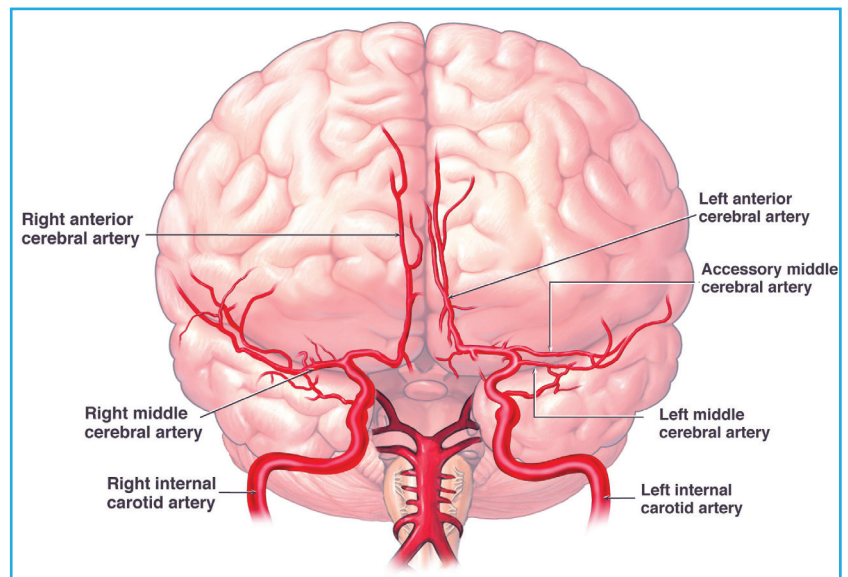


Image: Cerebral circulatory system. Illustration Copyright © 2019 Nucleus Medical Media, All rights reserved. www.nucleusmedicalmedia.com

Preparing for the treatment

The Medical Imaging department will give you instructions on how to prepare for the procedure. It is important to follow the instructions that are given to you.

This procedure will require the use of a local anaesthetic and possibly sedation or a general anaesthetic.

Tell the doctor/clinician if you:

- are breastfeeding or pregnant, or suspect that you may be pregnant.
- have a drug or medication dependence.

On the day of the treatment

- Nothing to eat or drink ('nil by mouth'): you will be told when to have your last meal and drink.
- Tell your doctor/clinician if you have:
 - health problems (e.g. diabetes, high blood pressure, infectious diseases, serious illnesses), including if undergoing regular treatment
 - had previous problems and/or known family problems with anaesthesia
 - been taking prescribed and/or over the counter medicines, herbal remedies and supplements; this may include and is not limited to blood thinning medicines, the contraceptive pill, antidepressants and/or medicine for treating diabetes (e.g. insulin)
 - false teeth, caps, loose teeth or other dental problems
 - allergies/intolerances of any type and their side effects.
- You will be required to change into a hospital gown and remove some of your jewellery. Your belongings will be kept in a safe location during the procedure.

Sedation

Sedation is the use of medicines that help make you feel relaxed and drowsy for your procedure. You may remember some or little about what has happened. You may still be aware of your surroundings and should be able to follow simple instructions, such as holding your breath when instructed by the doctor/clinician.

If you are booked for an anaesthetic or sedation, please read the information sheet *About Your Anaesthetic*. If you do not have one of these information sheets, please ask for one.

During the treatment

You will be transferred to the angiography room and onto a special procedure table.

Routine observations, such as heart rate and blood pressure, will be taken before the start, and regularly throughout, the procedure.

The skin of your groin area (or arm) will be cleaned, and a sterile drape will be applied to cover your body. The radiologist (doctor) will use local anaesthetic to numb the skin and make a small cut where the needle enters. Using ultrasound guidance, a needle, guidewire and catheter are inserted into the artery. Once the catheter is in place the needle is removed.

The doctor/clinician can guide the catheter up through the main vessels of your body using guidewires, x-ray and contrast, to the arteries that go to your brain.

Images are taken with x-ray while contrast is injected into these arteries, allowing the radiologist to locate the vessels that are in vasospasm. When these vessels are located, the medication will be slowly injected and/or the balloon will be inflated.

After the treatment, more contrast will be injected to allow the radiologist to further assess the blood flow through your brain.

When the procedure is finished the catheter will be removed. Firm pressure will be put over the area where the catheter went into your skin (puncture site), sometimes a special plug is used. This allows the artery to seal over so you will not bleed. A small dressing will be applied over the puncture site.

If repeated treatments are likely, the catheter will be removed but a sheath (small tube) may be left in place to allow future access to the artery. The sheath will be secured with a dressing and possibly a stitch.

After the procedure, you will be transferred and monitored in the Intensive Care Unit (ICU).

You will need to lie flat for up to 6 hours and keep your leg (or arm) still and straight. Moving too soon after the procedure may cause bleeding at the puncture site. If the sheath was left in then you will need to lie flat and keep your leg (or arm) still and straight for as long as it is in place. This may be up to several days.



2. What are the risks?

In recommending the treatment, the doctor/clinician believes that the benefits to you from having the treatment exceed the risks involved. There are risks and possible complications associated with the treatment which can occur with all patients – these are set out below. There may also be additional risks and possible complications specific to your condition and circumstances which the doctor/clinician will discuss with you. If you have any further concerns, please ensure that you raise them with the doctor/clinician prior to giving consent to the treatment.

Common risks and complications

- mild pain or discomfort may occur around the puncture site
- bleeding or bruising could occur at the puncture site. This is usually stopped by applying pressure and/or ice to the puncture site
- bleeding or bruising is more common if you have been taking blood thinning medicines, such as warfarin, aspirin, clopidogrel (Plavix, Iscover, Coplavix), prasugrel (Effient), dipyridamole (Persantin or Asasantin), ticagrelor (Brilinta), apixaban (Eliquis), dabigatran (Pradaxa), rivaroxaban (Xarelto) or complementary/alternative medicines, such as fish oil and turmeric
- failure of local anaesthetic which may require a further injection of anaesthetic or a different method of anaesthesia
- nerve damage, is usually temporary, and should get better over time. Permanent nerve damage is rare.

Uncommon risks and complications

- (*iodinated contrast only*) allergic reactions rarely occur, but when they do, they occur within the first hour, with most happening in the first five minutes. Late reactions have been known to occur up to 1 week after the injection, but these delayed reactions are usually mild. Note: Allergy to topical iodine and/or seafood does not imply an allergy to iodinated contrast. The reactions vary from:
 - mild: hives, sweating, sneezing, coughing, nausea

- moderate: widespread hives, headache, facial swelling, vomiting, shortness of breath
- severe: severe reactions are rare but include life-threatening heart palpitations, very low blood pressure, throat swelling, seizures and/or cardiac arrest
- the procedure may not be possible due to medical and/or technical reasons
- infection, requiring antibiotics and further treatment
- damage to surrounding structures, such as blood vessels, organs and muscles, requiring further treatment
- stroke from blood clots or damage to the artery, blocking the normal blood vessels in the brain. This can cause weakness in the face, arms and legs. This could be temporary or permanent
- failure of the treatment to improve the vasospasm or it may increase the severity of the already present vasospasm
- a blood clot or excessive bleeding from the puncture site. This may require other treatment and/or corrective surgery
- an allergy to injected medication, requiring further treatment
- temporary epilation (hair loss) from x-ray exposure.

Rare risks and complications

- rupture of a blood vessel during balloon inflation requiring other treatment and/or corrective surgery
- skin burns or permanent epilation (hairloss) from exposure to x-rays
- seizures and/or cardiac arrest due to local anaesthetic toxicity
- death because of this procedure is very rare.

Rare risks and complications of the medication used to treat vasospasm include:

- low blood pressure, which may require treatment with medications
- cardiac arrhythmias (changed heartbeat), which may require treatment with medications
- pressure increase in the fluid around the brain requiring medication and/or a temporary drain to be inserted.

Intravascular contrast and risk to kidney function

As contrast is not suitable for some people, you will be asked a series of questions before the contrast is given. The answers allow staff to identify any risk factors you may have.

Contrast is removed from the blood by the kidneys through the urine. It is easily removed from the body if you have normal kidney function. You may be asked to have a blood test to find out how well your kidneys are functioning.

When significant worsening of kidney function is seen, such as in kidney disease, there is often more than one factor causing stress to the kidneys such as certain medicines, infection, dehydration or low blood pressure. To minimise stress to your kidneys your doctor/clinician may recommend you have extra fluid to ensure good hydration, stop some medicines temporarily or have extra blood tests to monitor your kidney function around the time of your procedure.

The risk of kidney injury from the contrast used in cerebral vasospasm treatment is very low. In patients with severe renal impairment or acute kidney injury, careful weighing of the risk versus the benefit of iodinated contrast media administration needs to be undertaken. However, severe renal impairment should not be regarded as an absolute contraindication to medically indicated iodinated contrast media administration¹.

To minimise stress to your kidneys your doctor/clinician may recommend you have extra fluid to ensure good hydration, stop some medications temporarily or have extra blood tests to monitor your kidney function around the time.

Risks of radiation

The risks of radiation exposure from this treatment need to be compared to the risks of your condition not being treated. Exposure to radiation may cause a slight increase in the risk of cancer to you over your lifetime.

However, the potential risk is small compared to the expected benefit of this procedure².

What are the risks of not having a cerebral vasospasm treatment?

There may be adverse consequences for your health if you choose not to have the proposed treatment. Please discuss these with the referring doctor/clinician.

If you choose not to have the treatment, you will not be required to sign a consent form.

If you have signed a consent form, you have the right to change your mind at any time prior to the treatment. Please contact the doctor/clinician to discuss.



3. Are there alternatives?

Making the decision to have a procedure requires you to understand the options available. Please discuss any alternative procedure options with your doctor/clinician before signing the consent form.



4. What should I expect after the treatment?

Your doctor/clinician will discuss with you what level of activity is suitable after your treatment.

No unnecessary or strenuous activity for 4–5 days.

The puncture site may remain tender, swollen or bruised for a few days

On discharge, please go to your nearest Emergency department or GP if you develop any of the following:

- a cool or cold limb
- slurred speech, balance problems or trouble using your arm or leg
- pain unrelieved by simple pain relief medicines
- continuous bleeding or swelling at the skin puncture site in your groin or arm
- signs of infection such as redness, inflammation at the puncture site or fever.



5. Who will be performing the treatment?

Radiographers, doctors, nuclear medicine technologists, sonographers, nurses, and medical imaging assistants make up the medical imaging team. All or some of these professionals may be involved in your treatment.

A doctor/clinician other than the consultant/specialist may assist with/conduct the clinically appropriate procedure. This could include a doctor/clinician undergoing further training, however all trainees are supervised according to relevant professional guidelines.

If you have any concerns about which doctor/clinician will be performing the procedure, please discuss this with the doctor/clinician.

For the purpose of undertaking professional training in this teaching hospital, a clinical student(s) may observe medical examination(s) or procedure(s) and may also, subject to your consent, assist with/conduct an examination or procedure on you while you are under anaesthetic.

You are under no obligation to consent to an examination(s) or a procedure(s) being undertaken by a clinical student(s) for training purposes. If you choose not to consent, it will not adversely affect your access, outcome or rights to medical treatment in any way.

For more information on student care, please visit www.health.qld.gov.au/consent/students.



6. Where can I find support or more information?

Hospital care: before, during and after is available on the Queensland Health website www.qld.gov.au/health/services/hospital-care/before-after where you can read about your healthcare rights.

You can also see a list of blood thinning medications at www.health.qld.gov.au/consent/bloodthinner.

Further information about informed consent can be found on the Informed Consent website www.health.qld.gov.au/consent. Additional statewide consent forms and patient information sheets are also available here.

Staff are available to support patients' cultural and spiritual needs. If you would like cultural or spiritual support, please discuss this with your doctor/clinician.

Queensland Health recognises that First Nations People's culture must be considered in the patient's clinical care to ensure their holistic health and individual needs are met.



7. Questions

Please ask the doctor/clinician if you do not understand any aspect of this patient information sheet or if you have any questions about your proposed procedure.

If you have further questions prior to your appointment, please contact the Medical Imaging department via the main switchboard of the facility where your procedure is booked.



8. Contact us

In an emergency, call Triple Zero (000).

If it is not an emergency, but you have concerns, contact 13 HEALTH (13 43 25 84), 24 hours a day, 7 days a week.

References:

1. Iodinated Contrast Media Guideline, V2.3 The Royal Australian and New Zealand College of Radiologists, March 2018. Available from www.ranzcr.com/college/document-library/ranzcr-iodinated-contrast-guidelines
2. Australian Radiation Protection and Nuclear Safety Agency (ARPANSA). Ionising radiation in our everyday environment, 2021. Available from www.arpansa.gov.au