



Queensland Government

Thrombolysis (Catheter-Directed) Consent

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?

Complete for ADULT patient only

- 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:

Complete for CHILD/YOUNG PERSON patient only

- Yes Although the patient is a child/young person, the patient may be capable of giving informed consent and having sufficient maturity, understanding and intelligence to enable them to fully understand the nature, consequences and risks of the proposed treatment and the consequences of non-treatment – ‘Gillick competence’ (*Gillick v West Norfolk and Wisbech Area Health Authority* [1986] AC 112)
 → **GO TO section B**
- No Parent/legal guardian/other person* with parental rights and responsibilities to provide consent and complete this form
 → **COMPLETE section A**

*Formal arrangements, such as parenting/custody orders, adoption, or other formally recognised carer/guardianship arrangements. Refer to the Queensland Health ‘Guide to Informed Decision-making in Health Care’ and local policy and procedures. Complete the source of decision-making authority as applicable below.

If applicable, source of decision-making authority (*tick one*):

- Court order → Court order verified
 Legal guardian → Documentation verified
 Other person → Documentation verified

Name of parent/legal guardian/other person:

Relationship to child/young person:

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 OR substitute decision-maker OR parent/legal guardian/other person confirms the following procedure(s)

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

Thrombolysis (catheter-directed): Yes No

Site/side of treatment:

Name of referring doctor/clinician:

D. Risks specific to the patient in having a thrombolysis (catheter-directed)

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

E. Risks specific to the patient in not having a thrombolysis (catheter-directed)

(Doctor/clinician to document specific risks in not having a thrombolysis [catheter-directed]):

F. Alternative procedure options

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

DO NOT WRITE IN THIS BINDING MARGIN

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SW9620

THROMBOLYSIS (CATHETER-DIRECTED) CONSENT



Thrombolysis (Catheter-Directed) Consent

(Affix identification label here)

URN:

Family name:

Given name(s):

Address:

Date of birth:

Sex: M F I

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 OR substitute decision-maker OR parent/legal guardian/other person.

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

Name of doctor/clinician:

Designation:

Signature:

Date:

H. Patient OR substitute decision-maker OR parent/legal guardian/other person consent

I acknowledge that the doctor/clinician has explained:

- the 'Thrombolysis (Catheter-Directed)' 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 procedure options
- that there is no guarantee the treatment will improve the medical condition
- that if a life-threatening event occurs during the treatment:
 - an adult patient will be treated based on documented discussions (e.g. AHD or ARP [Acute Resuscitation Plan])
 - a child/young person's health care will be provided in accordance with good clinical practice and in the best interests of the patient
- 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/parent/legal guardian/other person have received the following consent and patient information sheet(s):

- 'Thrombolysis (Catheter-Directed)'
- 'About Your Anaesthetic' (*Adult patient only*)
- 'About Your Child's Anaesthetic' (*Child/young person patient only*)

On the basis of the above statements,

1) I/substitute decision-maker/parent/legal guardian/other person consent to having a thrombolysis (catheter-directed).

Name of patient/substitute decision-maker/parent/legal guardian/other person:

Signature:

Date:

If the patient is a child/young person:

- I am not aware of any legal or other reason that prevents me from providing unrestricted consent for this child/young person for this treatment (*not applicable if the child/young person is Gillick competent and signs this form*).

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 OR substitute decision-maker OR parent/legal guardian/other person consent, assist with/conduct an examination or procedure on a patient while the patient is under anaesthetic.

I/substitute decision-maker/parent/legal guardian/other person 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

Thrombolysis (Catheter-Directed)

Adult and Child/Young Person | Informed consent: patient information

A copy of this patient information sheet should be given to the patient or substitute decision-maker or parent/legal guardian/other person of a child or young person 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, parent, legal guardian or other person is providing consent on behalf of the patient, in which case the word 'you' means the substitute decision-maker, parent, legal guardian or other person when used in the context of the person providing consent to the treatment.



1. What is thrombolysis (catheter-directed) and how will it help me?

Thrombolysis is a treatment used to dissolve or break down a blood clot that is blocking the normal flow of blood in a vein or artery. 'Catheter-directed' means that the thrombolysis will be carried out by inserting a catheter (thin tube) into the blood vessel to deliver medication directly to the blood clot. Thrombolysis is used instead of surgery to treat blood clots.

Thrombolysis is performed as an extra step to an angiogram (or venogram) procedure. An angiogram (or venogram) is a procedure where x-rays and iodinated 'contrast' are used to examine blood vessels and to locate the blood vessels that are blocked.

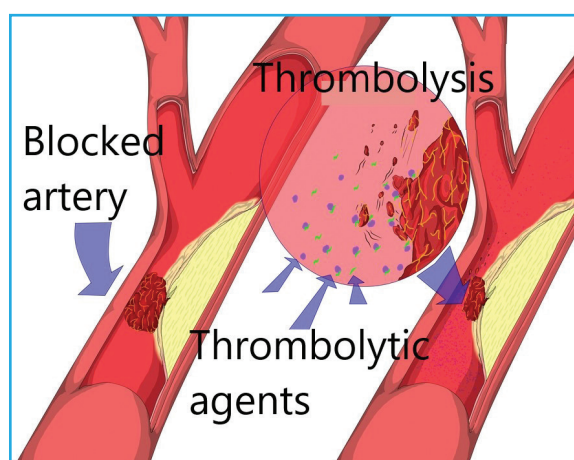


Image: Thrombolysis.
ID: 744484507 (adapted). www.shutterstock.com

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. Your procedure might be delayed if you don't follow all the preparation steps.

Medical imaging staff will notify you beforehand if you are required to stop taking any blood-thinning medicine. List or bring all your prescribed medicines, those medicines you buy over the counter, herbal remedies and supplements to show the doctor/clinician what you are taking.

This procedure will require the use of a local anaesthetic and possibly a mild sedation. If a patient is unable to co-operate under sedation (for example a child or young person), a general anaesthetic may be required. If you received sedation and are being discharged on the same day, you cannot drive and you must have someone available to escort you home.

Do not drink alcohol, smoke, vape or take recreational drugs for at least 24 hours before the procedure as these may alter the effects of the sedation anaesthetic. If you have a drug or medication dependence, please tell your doctor/clinician.

Please tell the doctor/clinician if you are breastfeeding or pregnant, or suspect that you may be pregnant.

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. Do NOT eat (including lollies), drink or chew gum after this time otherwise your procedure may be delayed or cancelled. This is to make sure your stomach is empty so that if you vomit, there will be nothing to go into your lungs.
- If you take medicines, most should be continued before a procedure and taken at the usual time, even on the day of the procedure, with a sip of water. There are some important exceptions:
 - your doctor/clinician will provide specific instructions about your medicines
 - take to the hospital all your prescribed medicines, those medicines you buy over the counter, herbal remedies and supplements. This may include and is not limited to blood thinning medicines, the contraceptive pill, antidepressants and/ or medicines for treating diabetes (e.g. insulin).
- If you feel unwell, telephone the medical imaging department for advice.
- 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
 - false teeth, caps, loose teeth or other dental problems
 - allergies/intolerances of any type and their side effects.
- You may be required to change into a hospital gown and remove some of your jewellery.

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 (for adults)* or *About Your Child's Anaesthetic (for child/young person)*. If you do not have one of these information sheets, please ask for one.

It is important that you lie still while the x-rays are being taken. Supporting straps, foam pads and light weights may be used.

For a parent/legal guardian/other person of a patient having thrombolysis (catheter-directed)

To prepare the patient for this treatment and to ease their concerns, tell them what they can expect to happen during the treatment. This information sheet will assist you with this.

We welcome your help and support in preparing the patient for the treatment and in explaining why it's so important to lie still.

If the patient is having a general anaesthetic you may be able to see them off to sleep. Once they are asleep you will be asked to leave the procedure room and wait in the waiting area.

Other children are not allowed into the treatment room, and they must be supervised at all times by another parent/ adult.

During the treatment

An intravenous (I.V.) cannula is a small plastic tube that will be inserted into a vein, usually in your hand or arm. This is for any medication or fluids required during the treatment, including sedation or anaesthetic.

Routine observations, for example blood pressure and heart rate, will be taken before the start of the treatment.

The skin in your groin (or arm, or back of leg) will be cleaned and a sterile drape will be applied to cover your body.

The doctor/clinician will use local anaesthetic to numb the skin and then make a small cut to allow access for a special needle into the vein or artery. Using iodinated contrast and

x-ray, the doctor/clinician will be able to guide a catheter up through the blood vessels to the area of interest. Once the catheter is in place the needle is removed.

You should not be able to feel the catheter inside your body.

X-ray images are taken while the contrast is being injected into your blood vessel. When the blood clot has been located the catheter will be placed directly into the clot or beside the clot.

An infusion of thrombolytic medication will be attached onto the end of the catheter to allow a slow but continuous infusion of the thrombolytic medication..

This infusion will continue for 12 to 72 hours.

While the infusion is going, you will be taken back to the ward. You will need to lie flat and keep your leg (or arm) still and straight.

Moving while the catheter is in your blood vessel may cause the catheter to dislodge from the clot and/or cause bleeding.

You will be closely monitored by nursing staff during the infusion. It is likely that you will not get much sleep during this time.

Thrombolysis check

You will be brought back to the Medical Imaging department to check the progress of the infusion.

This checking process may happen two or three times during the infusion.

The check will be done by briefly stopping the infusion and injecting contrast down the catheter and taking x-ray images to see how much of the blood clot has dissolved.

The catheter may need to be repositioned and the infusion will be recommenced.

Once the treatment is complete the catheter will be removed. Firm pressure will be applied over the area where the catheter went into your skin (puncture site). This allows the blood vessel to seal over so you will not bleed. A dry clear dressing will be applied to cover the puncture site.

You will then be transferred from the treatment room to a recovery area.

Your observations and groin (or arm/leg) puncture site will be monitored regularly for swelling, oozing of blood and bruising. Once stable, you will be transferred back to the ward.

You may be required to rest in bed for up to 6 hours. Moving too soon after this treatment may cause bleeding at the puncture site.

You may eat and drink after your procedure unless otherwise advised.

If the I.V. cannula is no longer required, it will be removed.



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

- minor pain, bruising and/or infection from the I.V. cannula
- pain or discomfort at the puncture site. This may require medication
- minor bleeding or bruising around the catheter site
- failure of the thrombolytic medication to completely dissolve the blood clot. Surgery may be required to remove the blood clot
- failure of local anaesthetic which may require a further injection of anaesthetic or a different method of anaesthesia may be used
- nerve damage, is usually temporary, and should get better over time. Permanent nerve damage is rare.

Uncommon risks and complications

- infection, requiring antibiotics and further treatment
- damage to surrounding structures such as blood vessels, organs and muscles, requiring further treatment
- stroke or spontaneous bleeding in other organs, such as stomach and bowel. This is due to the thrombolytic and blood thinning medications given during the treatment. The treatment will be stopped and surgery may be required to stop the bleeding
- a blood clot or excessive bleeding from the puncture site. This may require other treatment and/or corrective surgery
- pain in limb as blood clot breaks down. This may require medication
- an allergy to injected medication, requiring further treatment
- the treatment may not be possible due to medical and/or technical reasons.

Rare risks and complications

- skin burns or damage from exposure to x-rays
- (*I.V. 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. 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
- seizures and/or cardiac arrest due to local anaesthetic toxicity
- death because of this treatment is very rare.

If general anaesthetic or sedation is given, extra risks include:

- faintness or dizziness, especially when you start to move
- fall in blood pressure
- nausea and vomiting
- weakness
- heart and lung problems, such as heart attack or pneumonia
- stroke resulting in brain damage.

Contrast precautions for people with renal impairment

Contrast is removed from the blood by the kidneys through the urine.

You may be asked to have a blood test to find out how well your kidneys are functioning.

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 function impairment should not be regarded as an absolute contraindication to medically indicated iodinated contrast media administration¹.

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.

Risks of radiation

The risks of radiation exposure from this procedure 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 thrombolysis (catheter-directed)?

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

If you choose not to have the procedure, 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 procedure. 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 referring 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.

It is normal to experience some tenderness and bruising around the puncture site for about 24 to 48 hours. Simple pain relievers and ice packs may help this.

If you experience anything other than minor discomfort, you should return to the hospital where you had treatment or to your referring doctor/clinician to ensure there are no complications.



5. Who will be performing the treatment?

Doctors, radiographers, 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 journey.

A doctor/clinician other than the consultant/specialist may assist with/conduct the clinically appropriate treatment. 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 treatment, 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 Aboriginal and Torres Strait Islander patients will experience the best clinical care when their culture is included during shared decision-making.

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 treatment.

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