Thrombolysis- Peripheral (Catheter Directed)

A. Interpreter / cultural needs

An Interpreter Service is required? □ Yes □ No
If Yes, is a qualified Interpreter present? □ Yes □ No
A Cultural Support Person is required? □ Yes □ No
If Yes, is a Cultural Support Person present? □ Yes □ No

B. Procedure

The following will be performed (Doctor/doctor delegate to document – include site and/or side where relevant to the procedure)

Thrombolysis is the use of medication to dissolve or break down a blood clot that is blocking blood flow. ‘Catheter directed’ means that the thrombolysis will be carried out by inserting a catheter into the blood vessel to deliver the medication directly to the blood clot.

A thrombolysis is performed as an extra step to an angiogram procedure. An angiogram is a procedure where x-rays and Iodinated ‘Contrast’ are used to examine blood vessels and to locate the blood vessels that are blocked. Thrombolysis is used instead of surgery to treat blood clots. This procedure will require an injection of local anaesthetic.

C. Risks of the procedure

In recommending the Thrombolysis, the doctor believes the benefits to you from having this procedure exceed the risks involved. The risks and complications with this procedure can include but are not limited to the following.

Common risks and complications include:
- Minor pain, bruising and/or infection from the IV cannula. This may require treatment with antibiotics.
- Pain or discomfort at the puncture site. This may require medication.
- Minor bleeding or bruising around the catheter. This is usually stopped by applying pressure and/or ice to the catheter insertion 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.

Less common risks and complications include:
- A blood clot or excessive bleeding from the puncture site. This may require other treatment and/or corrective surgery.
- An allergy to injected drugs, requiring further treatment.
- Pain in limb as blood clot breaks down. This may require medication.
- The procedure may not be possible due to medical and/or technical reasons.

Rare risks and complications include:
- An increased lifetime cancer risk due to the exposure to x-rays.
- Skin burns or damage from exposure to x-rays.
- Seizures and/or cardiac arrest due to local anaesthetic toxicity.
- Death as a result of this procedure is very rare.
I request to have the procedure

Name of Patient: ..........................................................
Signature: ..................................................................
Date: ......................................................................

Patients who lack capacity to provide consent

Consent must be obtained from a substitute decision maker/s in the order below.

Does the patient have an Advance Health Directive (AHD)?

☐ Yes ▶ Location of the original or certified copy of the AHD:

☐ No ▶ Name of Substitute Decision Maker/s: ..........................................................
         Signature: ..................................................................
         Relationship to patient: ..........................................
         Date: ............................................................. PH No: ..................................
         Source of decision making authority (tick one):
         ☐ Tribunal-appointed Guardian
         ☐ Attorney/s for health matters under Enduring Power of Attorney or AHD
         ☐ Statutory Health Attorney
         ☐ If none of these, the Adult Guardian has provided consent. Ph 1300 QLD OAG (753 624)

F. Doctor/delegate Statement

I have explained to the patient all the above points under:

☐ the Patient Consent section (E)
☐ Iodinated Contrast - Patients with Renal Impairment Section (D) (for renal impaired patients only)

and I am of the opinion that the patient/substitute decision-maker has understood the information.

Name of Doctor/delegate: ..........................................
Designation: ..........................................................
Signature: .......................................................... Date: ..................................

G. Interpreter’s statement

I have given a sight translation in

(state the patient’s language here) of the consent form and assisted in the provision of any verbal and written information given to the patient/parent or guardian/substitute decision-maker by the doctor.

Name of Interpreter: ..........................................
Signature: .......................................................... Date: ..................................

Thrombolysis - Peripheral (Catheter Directed)

I acknowledge that the doctor/doctor delegate has explained the proposed procedure.

I understand;

- the risks and complications, including the risks that are specific to me.
- the anaesthetic required for this procedure. I understand the risks, including the risks that are specific to me.
- that no guarantee has been made that the procedure will improve my condition even though it has been carried out with due professional care.
- if immediate life-threatening events happen during the procedure, they will be treated based on my discussions with the doctor/doctor delegate or my Acute Resuscitation Plan.
- a doctor/doctor delegate undergoing further training may conduct this procedure.

I have been given the following Patient Information Sheet/s:
☐ Thrombolysis – Peripheral (Catheter Directed)
☐ Iodinated Contrast

☐ I was able to ask questions and raise concerns with the doctor/doctor delegate about the proposed procedure and its risks. My questions and concerns have been discussed and answered to my satisfaction.

☐ I understand I have the right to change my mind at any time including after I have signed this form but, preferably following a discussion with my doctor/doctor delegate.

☐ I understand that image/s or video footage may be recorded as part of and during my procedure and that these image/s or video/s will assist the doctor to provide appropriate treatment.

☐ I understand that Queensland Health may release my relevant de-identified information obtained from this and related procedures for education and training of health professionals.

On the basis of the above statements,

Specific Risks of Iodinated Contrast to patient’s identified as having Renal Impairment:

- Giving the Contrast to people with weakened kidneys (renal impairment), can cause further kidney damage, which may in turn cause the kidneys to stop working properly (acute renal failure).
1. What is Catheter Directed Thrombolysis?
Thrombolysis is the use of medication to dissolve or break down a blood clot that is blocking blood flow. ‘Catheter directed’ means that the thrombolysis will be carried out by inserting a catheter into the blood vessel to deliver the medication directly to the blood clot.
A thrombolysis is performed as an extra step to an angiogram procedure. An angiogram is a procedure where x-rays and Iodinated ‘Contrast’ (once called x-ray dye) are used to examine blood vessels and to locate the blood vessels that are blocked. This is done by placing a needle and a thin plastic tube (catheter) into the artery in your groin. Thrombolysis is used instead of surgery to treat blood clots.

For more information on Iodinated ‘Contrast’ and the risks involved in its use, please read the Iodinated Contrast Patient Information Sheet. (If you do not have this information sheet please ask for one).

2. Will there be any discomfort, is any anaesthetic needed?
This procedure will require an injection of local anaesthetic. It is used to prevent or relieve pain, but will not put you to sleep.

3. Preparation for the procedure
The medical imaging department will give you instructions on how to prepare for your procedure.
• Please tell the staff if you are or suspect you might be pregnant or are breastfeeding.

• If you take Aspirin, Warfarin, Clopidogrel (Plavix and Iscover) or Dipyridamole (Persantin and Asasantin) or any other drug that is used to thin your blood ask your doctor/health practitioner if you should stop taking it before the procedure as it may affect your blood clotting.

• List or bring all your prescribed drugs, those drugs you buy over the counter, herbal remedies and supplements.

• Do not drink any alcohol and stop recreational drugs 24 hours before the procedure as these may alter the affects of the sedation anaesthetic. If you have a drug habit please tell your doctor.

4. During the procedure
A fine needle (IV cannula) will be put into a vein in your arm.
The Radiologist (x-ray doctor) will perform an angiogram. This involves the injection of local anaesthetic into the skin. A needle and catheter are inserted into the artery in your groin; sometimes your arm may be used. Once the catheter is in place the needle is removed.
The catheter is guided through the main blood vessels in your body until it reaches the area to be studied. You should not be able to feel the catheter inside your body.
X-ray pictures are taken while the Contrast is injected into your arteries.
When the blood clot has been located the catheter will be placed directly into the clot or beside the clot.
Infusion of Thrombolytic Medication
An infusion (drip) will be attached onto the end of the catheter to slowly but continuously inject more 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. Be aware 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 pictures to see how much of the blood clot has dissolved.
The catheter may need to be repositioned and the infusion will be recommenced.
When the procedure is finished the catheter will be removed. Firm pressure will be put over the area.
5. After the procedure
The recovery time after the procedure varies between 4 to 6 hours.
You will need to lie flat and keep your leg (or arm) still and straight. Moving too soon after the procedure may cause bleeding at the puncture site.
The IV cannula will be removed after you have fully recovered.
Staff will discuss with you the need to restrict your activities for up to 5 days. Follow these instructions carefully.

6. What are the risks of this specific procedure?
The risks and complications with this procedure can include but are not limited to the following:

**Common risks and complications include:**
- Minor pain, bruising and/or infection from the IV cannula. This may require treatment with antibiotics.
- Pain or discomfort at the puncture site. This may require medication.
- Minor bleeding or bruising around the catheter. This is usually stopped by applying pressure and/or ice to the catheter insertion 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 a period of time. Permanent nerve damage is rare.

**Less common risks and complications include:**
- 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 procedure. The procedure 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.
- An allergy to injected drugs, requiring further treatment.

- Pain in limb as blood clot breaks down. This may require medication.
- The procedure may not be possible due to medical and/or technical reasons.

**Rare Risks and complications include:**
- An increased lifetime cancer risk due to the exposure to x-rays.
- Skin burns or damage from exposure to x-rays.
- Seizures and/or cardiac arrest due to local anaesthetic toxicity.
- Death as a result of this procedure is very rare.

Notes to talk to my doctor/ health practitioner about:
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1. What is Iodinated Contrast?
The medical imaging procedure your doctor has asked you to have uses iodinated ‘Contrast’ (once called X-ray dye). Contrast is a colourless liquid which includes iodine. Contrast is injected into your bloodstream to allow your organs to be seen more clearly on x-rays. Contrast is not a dye. It does not stain the inside of your body. Your doctor needs to use Contrast to be able to get all the information needed to assist with your diagnosis.

This information sheet must be read together with the information sheet of the procedure you are booked for (if you do not have this information sheet please ask for one).

2. During the procedure
When the Contrast is injected you may feel:
- A very warm or ‘flushed’ feeling over your body, this may also make you think you have passed urine. You will not pass urine – it is only a feeling.
- A ‘metallic’ taste or smell may also happen. This usually lasts less than a minute.

3. After the procedure
It is recommended that you drink 2 to 4 glasses of water after your procedure to help flush the Contrast from your body. Contrast does not affect your ability to carry out normal activities; you should be able to continue with your day as normal.

4. Precautions
Contrast is not suitable for some people; you will be asked a series of questions before it is given to you. Your answers allow staff to identify any risk factors that you may have.
- Please tell the staff if you are or suspect you might be pregnant or are breastfeeding.

Kidney function
- Contrast is removed from your blood by your kidneys through your urine. It is easily removed from the body of people who have normal kidney function.
- Giving Contrast to people with weakened kidneys (renal impairment), can cause further kidney damage, which may in turn cause the kidneys to stop working properly (acute renal failure).
- You may be asked to have a simple blood test to find out the level of their kidney function.

Diabetic Drug interactions - Metformin
(Other Drug names: Avandamet, Diabex, Diaformin, Formet, Glucohexal, Glucomet, Glucophage, Glucovance, Metforbell)

If kidneys suffer damage from the Contrast then the kidneys may not be able to remove Metformin from the body. It is safer to briefly stop taking Metformin when having Contrast. Staff will inform you when to stop and when it is safe to take Metformin again.

Contact your GP to monitor your diabetes if you are told to stop your Metformin.

5. What are the risks of Iodinated Contrast?
The risks and complications with this injection can include but are not limited to the following.

Common risks and complications include:
- No known common risks.

Less common risks and complications include:
- Injected Contrast may leak outside of the blood vessel, under the skin and into the tissue. This may require treatment. In very rare cases, further surgery could be required if the skin breaks down.
- Acute Renal Failure occurs when one or both of your kidneys suddenly stop working. Failure can last for days or weeks. It may take the kidneys a long time to regain their previous level of function and you may require dialysis to filter your blood during this time. There is a risk your kidneys could be permanently damaged. To reduce this risk the smallest possible dose of Contrast will be given.
- The injection may not be possible due to medical and/or technical reasons.

Rare risks and complications include:
- Allergic reactions occur within the first hour with most happening in the first 5 minutes. Late reactions have been known to occur up to a 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* – wide spread hives, headaches, facial swelling, vomiting, shortness of breath.
- *Severe* – Severe reactions are rare but include: life-threatening heart palpitations, very low blood pressure, throat swelling, fits and/or cardiac arrest.
- Death as a result of iodinated Contrast is very rare.

6. What are the safety issues when you leave the hospital?
Go to your nearest Emergency Department or GP if you become unwell.