



Queensland
Government

Trans-Arterial Chemo-Embolisation (TACE) 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 procedure 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:

Trans-Arterial Chemo-Embolisation (TACE): Yes No
Site/side of procedure:

Name of referring doctor/clinician:

D. Risks specific to the patient in having a Trans-Arterial Chemo-Embolisation (TACE)

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

E. Risks specific to the patient in *not* having a Trans-Arterial Chemo-Embolisation (TACE)

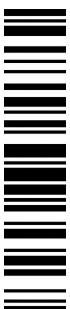
(Doctor/clinician to document specific risks in not having a Trans-Arterial Chemo-Embolisation [TACE]):

F. Alternative procedure options

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

DO NOT WRITE IN THIS BINDING MARGIN

v1.00
Clinical content review: 2023
Clinical check: 09/2023
Published: 09/2023



SW9619

TACE CONSENT



Trans-Arterial Chemo-Embolisation (TACE) 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 'Trans-Arterial Chemo-Embolisation (TACE)' patient information sheet
- the medical condition and proposed treatment, including the possibility of additional treatment
- the specific risks and benefits of the procedure
- the prognosis, and risks of not having the procedure
- alternative procedure options
- that there is no guarantee the procedure will improve the medical condition
- that the procedure may involve a blood transfusion
- that tissues/blood may be removed and used for diagnosis/management of the condition
- that if a life-threatening event occurs during the procedure:
 - 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 procedure; 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):

- 'Trans-Arterial Chemo-Embolisation (TACE)'
- 'About Your Anaesthetic' (*Adult patient only*)
- 'About Your Child's Anaesthetic' (*Child/young person patient only*)
- 'Blood and/or Manufactured Blood Products Transfusion (Full/Limited Consent)' (*Adult patient only*)
- 'Transfusion Consent: Fresh and/or Manufactured Blood Products (Full/Limited Consent)' (*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 Trans-Arterial Chemo-Embolisation (TACE).

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 procedure (*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

Trans-Arterial Chemo-Embolisation (TACE)

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 procedure.



1. What is a Trans-Arterial Chemo-Embolisation (TACE) and how will it help me?

Trans-Arterial Chemo-Embolisation (TACE) is a procedure to treat liver cancer. The goal of TACE is to reduce the size of the liver cancer. There are two ways in which the TACE does this:

1. Chemotherapy is directly delivered into the cancer to cause the destruction of cancer cells; and
2. The blood vessels supplying the cancer are blocked by a material called an embolic agent (known as embolisation).

This results in the chemotherapy being trapped inside the tumour without exposing the entire body to the effects of the chemotherapy. TACE may be used as a single treatment or in combination with surgery, ablation (the use of extreme heat or cold to treat lesions), chemotherapy that affects the whole body, or radiation therapy.

A team of doctors have looked at your recent scans and liver function test results and have decided that TACE is the best treatment for the cancer you have.

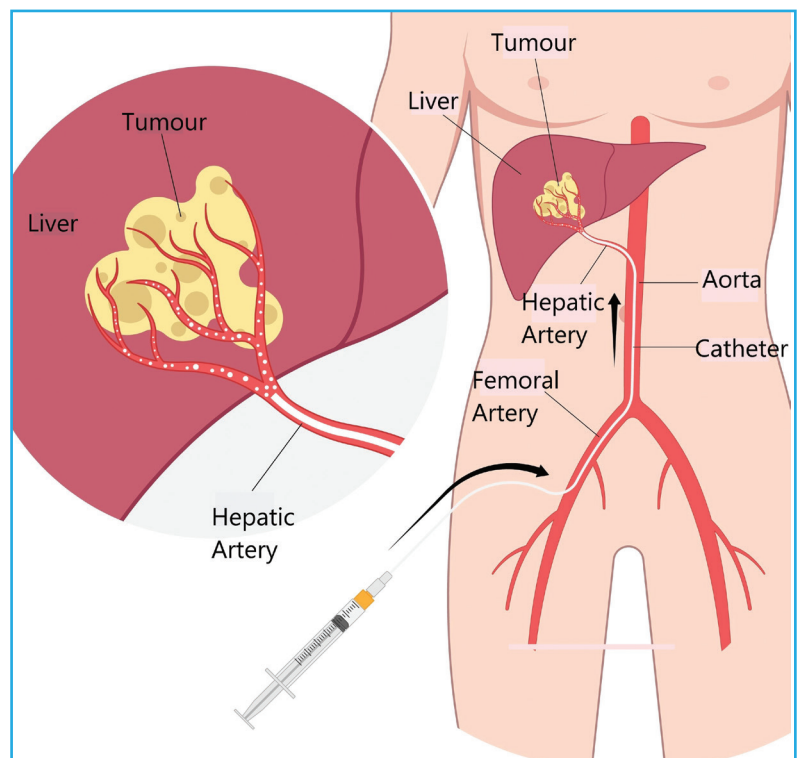


Image: Diagram of TACE. ID: 2162922401 (adapted). www.shutterstock.com

TACE is done by placing a needle and a thin plastic tube (catheter) into the artery in your groin (or arm). The catheter allows the doctor to use iodinated contrast (also known as x-ray dye) during the procedure to help map your arteries and locate and treat the tumour. Contrast is a colourless liquid. It does not stain the inside of your body.

Preparing for the procedure

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.

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 procedure

- 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 are taking 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 diabetic medicines (e.g. insulin).

- If you feel unwell, telephone the Medical Imaging department for advice.
- Tell your doctor/clinician and the nurse if you have:
 - health problems (e.g. diabetes, high blood pressure, infectious diseases, serious illnesses), including if regular treatment or a stay in hospital is needed
 - 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 side effects.
- You will 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.

For a parent/legal guardian/other person of a patient having TACE

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

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

At the discretion of the procedure staff:

- a parent/adult (unless pregnant) may be invited into the procedure room to support the patient

- 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 procedure room, and they must be supervised at all times by another parent/adult.

During the procedure

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 procedure, including sedation.

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

The skin in your groin area or arm 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 in your groin or arm, placing a special needle into the artery. Using iodinated contrast and x-ray images, the doctor will be able to guide a catheter up through the blood vessels to the liver. Once the catheter is in place the needle is removed.

It is very important that you lie very still while the x-rays are being taken.

The arteries to the liver will be mapped out during the procedure to ensure that the TACE treatment can be safely delivered to the liver and not to the surrounding structures such as the stomach or bowel. In some cases, small arteries may need to be blocked off by using metal coils to safely direct the particles to the liver.

When the catheter is in place the doctor/clinician will deliver the chemotherapy. Once the chemotherapy is in, the doctor/clinician will remove the plastic tube and catheter and press on your puncture site to stop any bleeding.

After the procedure is complete, you will be transferred from the procedure room to a recovery area.

Your observations and puncture site will be monitored regularly for swelling, oozing of blood and bruising. You may be required to rest in bed for up to 6 hours. Moving too soon after this procedure may cause bleeding at the puncture site.

Once your observations are stable, you will be transferred to a ward for an overnight stay.

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



2. What are the risks?

In recommending the procedure, the doctor/clinician believes that the benefits to you from having the procedure exceed the risks involved. There are risks and possible complications associated with the procedure 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 procedure.

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
- bleeding or bruising may occur at the puncture site. This is usually stopped by applying pressure and ice
- 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
- fatigue

- post-embolisation syndrome which includes pain, fever, nausea, vomiting and diarrhoea. Treatment may be required
- 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

- infection, requiring antibiotics and further treatment
- damage to surrounding structures such as blood vessels, organs and muscles, requiring further treatment
- a blood clot or excessive bleeding from the puncture site. This may require other treatment and/or corrective surgery
- an allergy to injected medications, requiring further treatment
- temporary epilation (hairloss) or skin damage, due to x-ray radiation to the treated area
- the procedure may not be possible due to medical and/or technical reasons.

Rare risks and complications

- the treatment and blockage of non-target arteries with potential damage to organs and tissue
- incomplete blocking of the flow of blood. This may require further procedures
- reactions to chemotherapy, including nausea, hair loss, a decrease in blood cell counts
- infection and/or damage to the liver resulting in liver failure. This will require further treatment
- 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 procedure is very rare.

If 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 patients 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 function 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 medications, 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 medications temporarily or have extra blood tests to monitor your kidney function around the time of your procedure.

Risk 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 TACE?

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 doctor/clinician before signing the consent form.



4. What should I expect after the procedure?

After the procedure, most patients experience some embolisation syndrome symptoms which include fatigue, pain, nausea, vomiting and fever. This is due to the blood supply to the treated area being cut off.

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

You will be able to go home once your pain and nausea have settled, usually within 2 days. It is normal to have a fever for up to a week after the procedure. Loss of appetite and fatigue are common and may continue for 2 weeks or longer.

Your healthcare team will discuss with you the need to restrict your activities at home for up to 5 days. Follow these instructions carefully.

Once you leave hospital, go to your nearest Emergency department or GP (your local doctor) if you become unwell or have:

- a cool or cold limb
- uncontrolled pain and/or nausea
- continuous bleeding, swelling, redness or inflammation at the puncture site
- high fever
- other warning signs the doctor/clinician may have asked you to be aware of.



5. Who will be performing the procedure?

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 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 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 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