Queensland	(Affix identification label here)
Government	URN:
	Family name:
Coronary Angiogram Consent	Given name(s):
Adult (18 years and over)	Address:
Facility:	
This consent form and patient information sheet uses th words 'l/you/your/me/my' to mean the patient or another person who is providing consent on behalf of the patient	angiogram
A. Does the patient have capacity to provide consent?	(Doctor to document additional risks not included in the patient information sheet)
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 substi decision-maker in the following order: Category 1. Tribun appointed guardian; 2. Enduring Power of Attorney; or 3. Statutory Health Attorney.	itute
Name of substitute decision-maker:	
Category of substitute decision-maker:	
B. Is an interpreter required?	
If <i>yes</i> , the interpreter has translated:	
A verbal translation is a summary of the form.	
Name of interpreter:	
National Accreditation Authority for Translators and	
Interpreters (NAATI) code:	
Interpreters (NAATI) code: Language:	
	E. Risks specific to the patient in <i>not</i> having a
	coronary angiogram
Language: C. Procedure details I confirm that the referring doctor has informed me abou	coronary angiogram (Doctor to document specific risks in not having a coronary
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Language: C. Procedure details I confirm that the referring doctor has informed me about following procedure(s) and I consent to: Coronary angiogram: Yes Intravascular Ultrasound (IVUS): Yes Optical Coherence Tomography (OCT): Yes Fractional Flow Reserve (FFR): Yes	<pre>coronary anglogram (Doctor to document specific risks in not having a coronary anglogram) </pre>
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DO NOT WRITE IN THIS BINDING MARGIN

v6.00 Clinical content review: 2024



Coronary Angiogram Consent Adult (18 years and over)	Given Addre			-	of Queensland (Queensland Health) 2024 <i>ght Act 1968</i> , no part of this work may be hout permission from Queensland Health ssion email: ip_officer@health.qld.gov.au
	Date	of birth:		M []F []I	 State o Copyrig Copyrig the with
F. Alternative procedure options (Doctor to document alternative procedure not included patient information sheet)	in the	I have received the following of information sheet(s):		ucts Transfusion	© The S Except as permitted under the c reproduced, communicated or adapt To request.
G. Acknowledgment and consent I acknowledge that the doctor has explained and I under	rstand:	On the basis of the above state	ments		בוט
the 'Coronary Angiogram' patient information sheet		I consent to having a coronar		ım.	
the medical condition and proposed procedure, include the possibility of additional treatment	ding	Name of patient/substitute decis	sion-maker:		
this procedure requires sedation or general anaesthe	tic	Signature:		Data:	
 the specific risks and benefits of the procedure the prognosis and risks of not having the procedure 		Signature:		Date:	
alternative procedure options		H. Doctor confirms			2
that there is no guarantee the procedure will improve medical condition	the	I have explained to you the cont	tents of this	form and am of	
that if the procedure leads to the need for a blood or products transfusion, an additional consent form will l required		the opinion that the information Name of doctor:	has been u	nderstood.	
 that if an immediate life-threatening event happens during the procedure, health care will be provided bas on my AHD (Advance Health Directive) or ARP (Acute 		Designation:]	
Resuscitation Plan). If no AHD or ARP is in place, here	alth	Signature:		Date:	
care will be provided in accordance with good clinical practice and the <i>Guardianship and Administration Ac</i>					
(<i>Qld</i>) that a doctor other than the consultant/specialist may		I. Clinical student involvem	nent		
assist with/conduct the clinically appropriate procedur		For the purpose of undertaking may observe medical examinati			
this may include a doctor undergoing further training u supervision	linder	may also, subject to my consent	t, assist wit	h/conduct an	
that if the doctor wishes to record video, audio or ima during the procedure where the recording is not requi		examination or procedure on me sedation or anaesthetic.	e/the patier	it while under	
as part of the treatment (e.g. for training or research		I consent to a clinical student(s)	-		
purposes), I will be asked to sign a separate consent If I choose not to consent, it will not adversely affect n	ny	 observe examination(s)/proced assist with examination(s)/proc 	. ,	☐ Yes ☐ No ☐ Yes ☐ No	
access, outcome or rights to medical treatment in any	way.	conduct examination(s)/proced	dure(s):	Yes No	
 I was able to ask questions and raise concerns with t doctor. I understand I have the right to change my mind regative concerns with the right to change my mind regative concerns. 		Note: you will also have the opp to student involvement, on the o For further information please so	lay of your	procedure.	
consent at any time, including after signing this form.		consent/students			



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

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This patient information sheet has been given to you to read carefully and allow time to ask your doctor any questions about this procedure. Your doctor will include the consent form and a copy of this patient information sheet in your medical record.

This patient information sheet uses the words 'l/you/your/me/my' to mean the patient or another person who is providing consent on behalf of the patient.

1. What is a coronary angiogram and how will it help me?

A coronary angiogram is a procedure when x-rays and iodinated contrast (also known as x-ray dye) are used to examine the coronary arteries (blood vessels of your heart). As the contrast moves through your blood vessels, the doctor watches its flow and identifies any abnormalities, blockages or narrowing in your vessels.

To help with the procedure, images may be taken, and tests done, to identify any abnormalities. These are done while the catheter is in the artery of interest. These may include:

- Intravascular Ultrasound (IVUS): Uses sound waves to produce an image
- Optical Coherence Tomography (OCT): Uses light to produce an image
- Fractional Flow Reserve (FFR): Compares blood flow on either side of the blockage in your coronary artery to show how severe the narrowing (stenosis) is.

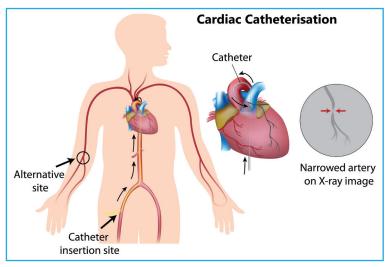


Image: Cardiac catheterisation. ID: 127004951. www.shutterstock.com

Preparing for the procedure

Patients having this procedure are usually in hospital for one day. Your doctor will be able to confirm that this estimate is likely to be true for your procedure.

The Cardiology 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.

Cardiology staff will notify you beforehand if you are required to stop taking any blood-thinning medication.

This procedure will require the use of a local anaesthetic and possibly a mild sedation. If you are having sedation and are being discharged on the same day, you cannot drive and you must have someone available to escort you home.



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

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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.

Please tell the doctor if you:

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

On the day of your 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 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 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 Cardiology department for advice.
- Tell your doctor 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 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.

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.

For a substitute decision-maker of an adult without capacity to consent to having a coronary angiogram

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.

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.

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



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

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 medication or fluid required during the procedure, including sedation.

Routine observations will be measured before and during the procedure, these may include cardiac rhythm, blood pressure, heart rate, respiratory (breathing) rate and oxygen levels.

The skin over your lower arm and/or groin will be cleaned and a sterile drape will cover your body.

The doctor 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. An access port, a thin hollow tube called a sheath, will be placed in the artery to allow equipment to be inserted into your vessel. Using contrast and x-ray guidance, the doctor will guide a catheter, via the sheath, up through the blood vessels into each coronary artery.

Images are taken as contrast is injected through the catheter. This will require the imaging equipment to move externally around your body. It is normal for the contrast to give you a warm flushed feeling while it is being injected.

While the catheter is in the artery an IVUS/ OCT/FFR (*see page 3*) may be performed, to help provide more information about the coronary arteries.

The contrast may then be injected into the main pumping chamber of the heart (left ventricle). This is to measure the size of the heart, and see how well it is pumping.

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At the end of the procedure, the sheath will be removed and the artery will be closed with pressure or a special plug to stop the 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 2 to 4 hours. Moving too soon after this procedure may cause bleeding at the puncture site.

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



2. What are the risks?

In recommending the procedure, the doctor 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.

Your doctor will discuss any additional risks, specific to your individual condition and circumstances, with you. These should be written on the consent form before you sign it.

Common risks and complications

- bleeding or bruising could occur at the puncture site. This is usually stopped by applying pressure and/or ice to the puncture site
- loss of pulse in the arm after a radial artery is used for procedural access. This could be temporary or permanent
- vasospasm, which usually resolves with time
- failure of local anaesthetic, which may require a further injection of anaesthetic or a different anaesthesia



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

• nerve damage, is usually temporary, and should get better over time.

Uncommon risks and complications

- infection, requiring antibiotics and further treatment
- serious bleeding, where the catheter was inserted. Serious bleeding in the brain, stomach or abdominal cavity may need surgical or endoscopic procedures to correct. Blood transfusion may be needed
- bleeding or bruising is more common if you have been taking blood-thinning medicines, such as warfarin, aspirin, clopidogrel (Plavix, Iscover), prasugrel, dipyridamole (Persantin), ticagrelor (Brilinta), apixaban (Eliquis), dabigatran (Pradaxa), rivaroxaban (Xarelto) or complementary/alternative medicines, such as fish oil and turmeric
- the procedure may not be possible due to medical and/or technical reasons.

Rare risks and complications

- abnormal heart rhythm, which may need an electric shock to correct
- damage to the artery in the leg or arm where the tubes are inserted. This may need surgical repair
- permanent damage to the nerve in the leg or arm where the tubes were inserted
- *(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 mild.
- a stroke. This can cause long term disability
- heart attack
- emergency heart surgery due to complications with the procedure
- a reaction to the medications given to prevent blood clotting

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- rupture or a tear of a blood vessel requiring surgical repair and blood transfusion
- skin burns or damage from exposure to x-rays
- death is possible due to the procedure or other heart problems.

If a 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 a heart attack or pneumonia
- stroke resulting in brain damage.

Iodinated contrast and risk to kidney function

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 actively deteriorating renal function (acute kidney injury) careful weighing of the risk versus the benefit of giving iodinated contrast, needs to be undertaken. However, severe renal function impairment does not mean that iodinated contrast should not be given, if medically indicated¹. Your treating doctor will discuss your specific circumstances with you.

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



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

the risk of cancer to you over your lifetime.
However, the potential risk is small compared
to the expected benefit of this procedure ² .

What are the risks of not having a coronary angiogram?

There may be adverse consequences for your health if you choose not to have the proposed procedure. You and your doctor should discuss these.

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.



Making the decision to have a procedure requires you to understand the options available. Your doctor will discuss any alternative procedure options and their risks or benefits with you, before signing the consent form.

4. What should I expect after the procedure?

Your healthcare team will talk to you about what to expect after your procedure and upon discharge from hospital.

Go to your nearest Emergency department or GP (your local doctor) if you become unwell or have:

- pain unrelieved by simple pain relievers or those prescribed for you
- bleeding, swelling, redness or inflammation at the puncture site
- a fever
- other warning signs the doctor may have asked you to be aware of.

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If you had sedation or an anaesthetic, this will affect your judgement for about 24 hours. For your own safety:

- Do NOT drive any type of car, bike or other vehicle.
- Do NOT operate machinery including cooking equipment.
- Do NOT make important decisions or sign a legal document.
- Do NOT drink alcohol, smoke, vape or take recreational drugs. They may react with the anaesthetic medications.

5. Who will be performing the procedure?

Doctors, cardiac scientists, radiographers, sonographers, pharmacists, nurses, patient support officers and administration staff make up the cardiology team. All or some of these professionals may be involved in your journey.

A doctor other than the consultant/specialist may assist with/conduct your procedure. This could include a registered doctor who is undergoing further training. All trainees are supervised according to relevant professional guidelines.

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

Clinical students

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



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

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Family name:					
Given name(s):					
Address:					
Date of birth:		Sex: M F I			

You are under no obligation to agree to an examination(s) or a procedure(s) being observed or 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 <u>www.health.qld.gov.au/consent/students</u>

6. Where can I find support or more information?

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

Queensland Health respects the privacy of patients and their families. To learn more about health records and personal information visit our website <u>www.health.qld.</u> <u>gov.au/system-governance/records-privacy/</u> <u>health-personal</u>

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

Further information about informed consent can be found on the Informed Consent website <u>www.health.qld.gov.au/</u> <u>consent</u>. 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.

Queensland Health recognises that First Nations Peoples' 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 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 Cardiology department via the main switchboard of the facility where your procedure is booked.



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:

 Australian Radiation Protection and Nuclear Safety Agency (ARPANSA). Ionising radiation in our everyday environment, 2021. Available from <u>www.arpansa.gov.au</u>

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Coronary Angiogram Patient Information

^{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/iodinated-contrast-guidelines-2016