Queensland Government

Yttrium-90 Colloid Therapy 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:

Yttrium-90 colloid therapy: ☐ Yes ☐ No

Name of referring doctor/clinician:

D. Risks specific to the patient in having Yttrium-90 colloid therapy

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

Pregnancy/breastfeeding questions for the patient

If you are pregnant, this procedure would generally not be performed unless the benefits outweigh the risks of having the procedure.

1. a) Are you pregnant? ☐ Yes ➔ ***GO TO** Q2*
   ☐ No ➔ ***GO TO** Q2*
   ☐ Possibly ➔ ***GO TO** Q1b*

   b) If required before the scan, do you agree to have a:
   Urine pregnancy test: ☐ Yes ☐ No
   Blood pregnancy test: ☐ Yes ☐ No

If you might be pregnant, further discussion with a doctor/ clinician will be provided to assist you in making an informed decision on continuing with the procedure.

2. Are you breastfeeding? ☐ Yes ☐ No

The doctor/clinician will review these answers and, if required, obtain further advice from a doctor or another clinician regarding your pregnancy and/or breastfeeding status prior to the scan.

E. Risks specific to the patient in *not* having Yttrium-90 colloid therapy

(Doctor/clinician to document specific risks in not having Yttrium-90 colloid therapy):

DO NOT WRITE IN THIS BINDING MARGIN

YTTRIUM-90 COLLOID THERAPY CONSENT

v1.00
Clinical content review: 2023
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SW9602

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URN:

Family name:

Given name(s):

Address:

Date of birth: Sex: ☐ M ☐ F ☐ I

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 *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 'Yttrium-90 Colloid Therapy' 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 tissues/blood may be removed and used for diagnosis/management of the 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/parent/legal guardian/other person have received the following consent and patient information sheet(s):

☐ 'Yttrium-90 Colloid Therapy'

On the basis of the above statements,

1) I/substitute decision-maker/parent/legal guardian/other person consent to having Yttrium-90 colloid therapy.

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

DO NOT WRITE IN THIS BINDING MARGIN

Yttrium-90 Colloid Therapy

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

Queensland Government

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.

This treatment uses a product that is not registered by the Australian Therapeutic Goods Administration (TGA). It has undergone little or no evaluation of safety, efficacy, or quality by the TGA. It may have unknown risks and late side effects. Extra information about your treatment will be given to you at the time of your appointment.

1. What is Yttrium-90 colloid therapy and how will it help me?

In Yttrium-90 colloid therapy, a dose of radiation is injected into the joint to assist with the control of swelling and pain associated with some types of arthritis.

Yttrium-90 colloid therapy may relieve symptoms such as pain and swelling. However, it is unlikely to slow or stop the damage caused to the joint by arthritis. It may take up to 2 weeks before any relief occurs.

A gamma camera may be used to take images 3 to 4 hours after the injection of Yttrium-90 to ensure that the dose is in the joint. A gamma camera (the scanner) takes images of the radiation as it is emitted from the fluid in and around the treated joint.

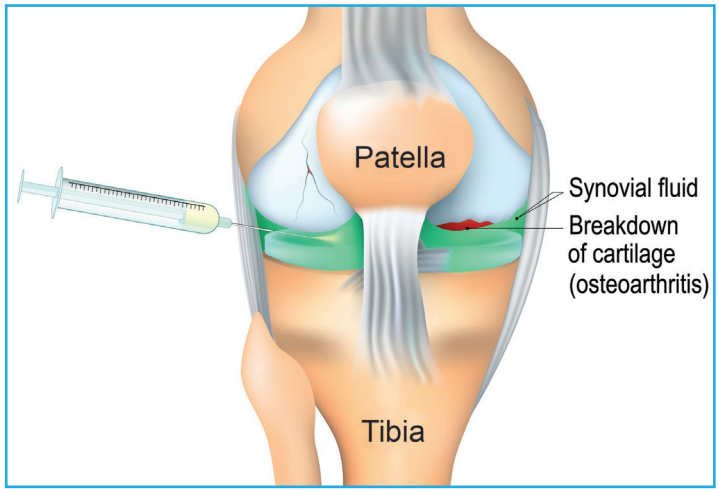

Image: Knee injections. ID: 1930923830 (adapted). www.shutterstock.com

Preparing for the treatment

The Nuclear Medicine department will give you instructions on how to prepare for your treatment.

Please tell the doctor/clinician if you are breastfeeding or pregnant or suspect that you may be pregnant. A blood test may be required to confirm pregnancy status.

Nuclear Medicine staff will notify you beforehand if you are required to stop taking any blood-thinning medication. List or bring all your prescribed medications, those medications you buy over the counter, herbal remedies and supplements.

For a parent/legal guardian/other person of a patient having Yttrium-90 colloid therapy

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.

At the discretion of the procedure staff a parent/adult (unless pregnant) may be invited into the treatment room to support the patient.

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

During the treatment

For the treatment, you will be positioned on an examination bed.

Local anaesthetic will be injected near the joint and below the skin to numb the area. This may sting for 10 to 20 seconds.

Once the skin is numb, a needle is put into the joint. Sometimes imaging is used to position the needle into the joint.

When the needle is in the joint, the Yttrium-90 colloid is injected into the joint, followed by an injection of steroids to help reduce the inflammation.

The needle is removed, a firm bandage applied, and a splint fitted to keep the joint immobile.

After 3 to 4 hours, some images may be taken with a gamma camera to make sure the Yttrium-90 is in the joint.

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

- the therapy may not reduce the pain or swelling in the joints. This is more common, the more worn and damaged the joint is
- pain or discomfort may be experienced during the therapy. The local anaesthetic may assist with this
- an allergy to injected medications may occur, requiring further treatment
- bleeding or bruising could occur
- bleeding 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
- nerve damage is usually temporary and should get better over time. Permanent nerve damage is rare.

Uncommon risks and complications

- temporary increase in joint pain and swelling after the procedure
- damage to surrounding structures such as blood vessels and muscles. This may require corrective surgery
- if the needle is not able to be positioned into the joint, imaging may be needed
- infection at the injection site requiring treatment
- the procedure may not be possible due to medical and/or technical reasons.

Rare risks and complications

- an allergy to injected radioactive tracers may occur, requiring further treatment
- injected Yttrium-90 may leak outside of the joint, under the skin and into the fat tissue, causing radiation damage to the tissue. This may require treatment. In very rare cases, surgery could be required
- blood clots can form in the treated limb, causing pain and swelling. In rare cases part of the clot may break off and go to your lungs
- if the access into the joint is unsuccessful the treatment may need to be abandoned
- death because of this therapy is very rare.

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 treatment[1].

What are the risks of not having Yttrium-90 colloid therapy?

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 treatment 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?

After the treatment the Nuclear Medicine department will talk to you about what to expect after the procedure.

Try to keep off and avoid using the injected limb for the first 48 hours after the injection.

Wiggle your toes or fingers at least once per hour to prevent blood clots forming in the injected limb.

If the bandage or splint feels too tight, your feet or hands feel numb or cold, or look pale or blue, please loosen or remove the splint and bandage and contact your Rheumatologist's office.

The splint, bandages and dressings can be removed after 48 hours. The bandages and dressing must be placed in a plastic bag, tied up and disposed of in the household rubbish.

Wash your hands after handling the bandages and dressings.

Contact your GP (your local doctor) or go to the nearest Emergency department if you become unwell or:

- you have an increase in joint pain that is not relieved by usual pain medications
- the joint becomes very red and swollen.

5. Who will be performing the treatment?

Nuclear medicine scientists/technologists, doctors and nurses make up a Nuclear Medicine 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 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.

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 recognise 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 treatment.

If you have further questions prior to your appointment, please contact the Nuclear Medicine 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. Australian Radiation Protection and Nuclear Safety Agency (ARPANSA). Ionising radiation in our everyday environment, 2021. Available from www.arpansa.gov.au