

Implantation of a Cardiac Resynchronisation Therapy-Defibrillator (CRT-D)

Consent information for patients



Your doctor has recommended that you are fitted with a Cardiac Resynchronisation Therapy-Defibrillator (CRT-D). A CRT-D is a small, metal, battery-powered device. CRT devices are used to help treat heart failure (when the heart does not pump as well as it should) by acting as a pacemaker and stimulating the heart chambers to pump at the same time. The defibrillator function sends impulses (fast pacing) to your heart muscle when your heart beats too quickly (which can cause life-threatening heart rhythms). These life-threatening heart rhythms are called ventricular tachycardia (VT) and ventricular fibrillation (VF). If your heart continues to beat too quickly, it will then give shock treatment to your heart.

The procedure is usually carried out using local anaesthetic (to make your skin and the area below go numb), pain relief and sedation (to make you feel drowsy). Depending on your medical history, your cardiologist may recommend that you are given a general anaesthetic (where you will be completely asleep). Your cardiologist will discuss which of these is the most suitable for you to have.

How do I prepare for the procedure

We will let you know before you come for the procedure (usually by letter), whether there are any specific instructions you need to follow. The letter will include important directions for stopping eating and drinking.

Please make sure you have a shower, bath or wash before you come into hospital/on the ward before your procedure. This helps to make sure your skin is clean and reduces the risk of infection.

What happens before the procedure?

The doctor (or nurse) will explain the procedure to you, including the risks and benefits. You will then be asked to sign a consent form to confirm you are happy for the procedure to go ahead.

You will need to change into a hospital gown for the procedure. You may be able to keep your underwear on as long as it contains no metal (such as sequins or poppers).

Before the procedure, a small plastic tube (called a cannula) will be inserted in your arm, so that we can give you antibiotics (to reduce the risk of infection), pain relief and sedation during the procedure. The sedation will make you feel relaxed and sleepy but you will not be fully asleep.

If you have any concerns, please do not hesitate to ask, as we would like you to be as relaxed as possible about the procedure. We will be happy to answer any queries you may have.

What happens during the procedure?

You will be asked to lie on your back on a narrow, firm table, which is positioned under an X-ray camera. This is used to help guide the doctor during the implantation. It is important that you lie still during the procedure, so that the pictures produced by the X-ray are not blurred. If you feel that you need to move or scratch an itch, please let the staff know.

We will connect you to monitoring equipment to check on your heart rate, blood pressure and the level of oxygen in your blood. A specialist nurse or an anaesthetist will give you the sedation medicine or general anaesthetic and will watch over you very closely.

We will clean your skin with an antiseptic solution, which may feel cold and wet, and your chest will be covered in sterile drapes. This helps us to keep the wound as clean as possible. You will be given a local anaesthetic, which will be given as an injection under your skin and below your collar bone on the side where your CRT-D will be placed. This may sting at first, but will soon go numb.

The CRT-D will be implanted under your skin in a pocket that the cardiologist will make in front of the muscle on the left or right of your upper chest (usually on the left). Occasionally it is implanted under the muscle layer. As with any surgical procedure, there will be a visible scar, and there may be a small bump where the CRT-D is placed.

The CRT-D will then be connected to your heart using two or three flexible leads that pass through a vein under your collar bone. The cardiologist will insert the leads into your heart using X-ray images to guide them. Moving the leads inside your heart is completely painless.

During the procedure we may need to test the shock function of the CRT-D. This will depend on your medical history. At this point

you will be given more sedation and we will 'bring on' a life-threatening heart rhythm (VF) under controlled circumstances. The CRT-D will be programmed to treat the heart rhythm with shock therapy.

When the CRT-D has been implanted (and tested if needed) the wound will be closed using a single long stitch in the skin, rather than lots of small stitches. This may be a non-dissolvable stitch, which will need to be removed by the Practice Nurse at your GP's surgery, or may be a dissolvable stitch, which will disappear over the next few weeks. You will be told which stitch you have and what you need to do before you are discharged.

The wound will be covered by a dressing. Please keep it covered for seven days. During this time, try to avoid getting the dressing very wet. You will need to have a wash, rather than a shower or bath. After seven days you can remove the dressing and bath and shower as normal. If at any point you have any concerns about your wound, please see your practice nurse or GP.

The procedure time varies, but can take around two to three hours.

Benefits

The main benefit of CRT is that it makes your heart chambers pump synchronously (at the same time). You may feel less breathless and have more energy.

The main benefit of the defibrillator function is that it works to protect you from the risk of sudden cardiac death due to dangerously fast heart rhythms (VT or VF). The defibrillator can also treat some rhythm disturbances without you being aware of it by fast pacing, and without shocks.

Risks

All medical procedures have a risk of complications. There are some risks associated with implantation of a CRT-D that are important to know about.

- There is a 1% (1 in 100) risk of developing a collapsed lung (pneumothorax) as a result of a lead perforating (making a hole in) the lung. This often requires no treatment, but you may need a tube called a chest drain to be inserted to help reinflate your lung.
- There is a 1% (1 in 100) risk of developing a collection of blood around your heart (cardiac tamponade), as a result of a small hole being made to the inner lining of your heart during the procedure. This often requires no treatment, but you may need to have a small drain inserted to drain away the blood.
- There is a 3-4% (3-4 in 100) risk of one of the leads becoming dislodged. If this happens, the lead will need to be repositioned soon after the CRT-D is implanted. We will carry out a chest X-ray to check for this after the procedure.
- There is a 3-4% (3-4 in 100) risk of the lead failing (not working). We would need to replace the lead during a further procedure.

- There is a 3-4% (3-4 in 100) chance that you may be unable to have the left ventricular lead implanted. We would still implant the device, but just with one or two leads. This will be explained to you before you sign the consent form.
- There is a 5% (5 in 100) risk of receiving an inappropriate shock from the defibrillator.
- There is a 3% (3 in 100) risk of developing an arrhythmia (altered heart rhythm) during the procedure.
- Bruising over and around the CRT-D site is common, but not usually serious. About 5% (5 in 100) of people develop a collection of blood, called a haematoma, over the CRT-D. This normally goes away on its own, but occasionally will need to be drained.
- There is an 0.5% (1 in 200) risk of the area around the CRT-D and/or the leads becoming infected after implantation, which then results in the CRT-D and leads being removed (extraction). To reduce this risk, you will be treated with antibiotics before and after the implantation.
- There is a 0.1 (1 in 1,000) risk of death from this procedure.
- 3-4% (3-4 in 100) people do not have an improvement in their symptoms from CRT.
- You will experience pain from this procedure. We strongly advise that you take regular painkillers to help with this, which we will provide.

Your doctor will recommend that you have a CRT-D if they feel the benefits of the procedure clearly outweigh the risks. The figures quoted in this document are average figures for all cases. Your doctor will discuss with you any specific risks that may apply to you, before the procedure.

Alternatives

Your doctors have recommended that this is the most appropriate treatment for your condition. If you wish to discuss alternatives, please talk to the doctor before you sign the consent form.

What happens after the CRT-D implantation?

Once you are fully awake, you should be able to eat and drink. The CRT-D will be checked the following working day, to make sure it is working correctly. You will also have a chest X-ray to confirm everything is in the right place and there are no complications. If everything is well you are likely to be able to go home.

You will need to travel home with a relative or friend. You should not go home on public transport after this procedure. You will need to be taken home by car. This will be more comfortable for you and also quicker for you to return to the hospital if there are any complications on the journey home.

Driving

After having a CRT-D implantation, there will be driving restrictions in line with the DVLA. We will be able to give you advice on these restrictions before you go home.

If you hold an HGV or PSV licence you will be permanently barred from driving HGVs or PSVs. If you have a taxi licence you will need to speak to your taxi licencing authority.

Follow-up appointments

You will normally be seen in the ICD outpatient clinic after approximately eight weeks and then usually every six months after this. This is to check that the CRT-D is working well and monitor the recorded information. We may be able to give you a home monitor to do this. This would mean that you could monitor the CRT-D and battery from home. This may be more convenient than having to visit the hospital and means we can check your CRT-D more frequently.

When the time comes for the battery (generator) to be replaced, you will need to come into hospital for a small operation for a new CRT-D generator to be fitted.

How to contact us

Cardiac Rhythm Management Office

01865 220 981

(Monday to Friday, 9.00am to 5.00pm)

Cardiac Angiography Suite

01865 572 615

(Monday to Friday, 7.30am to 9.00pm)

Cardiology Ward

01865 572 675

(24 hours)

ICD Nurses

01865 221 667

(Monday to Friday, 8.00am to 5.00pm)

Further information

For further information, we recommend the following websites:

British Heart Foundation

Tel: **0300 330 3322**

Website: **www.bhf.org.uk**

British Cardiovascular Society

Website: **www.bcs.com**

Arrhythmia Alliance

Tel: **01789 867 501**

Website: **www.heartrhythmcharity.org.uk**

Please note:

The department where your procedure will take place regularly has professional observers. The majority of these observers are health care professionals, qualified or in training and on occasions, specialist company representatives. If you do not wish observers to be present during your procedure please let a doctor or nurse know.

If you have a specific requirement, need an interpreter, a document in Easy Read, another language, large print, Braille or audio version, please call **01865 221 473** or email **PALS@ouh.nhs.uk**

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www.ouh.nhs.uk/information

