Department of urology

NanoKnife focal irreversible electroporation (IRE) for the treatment of the prostate

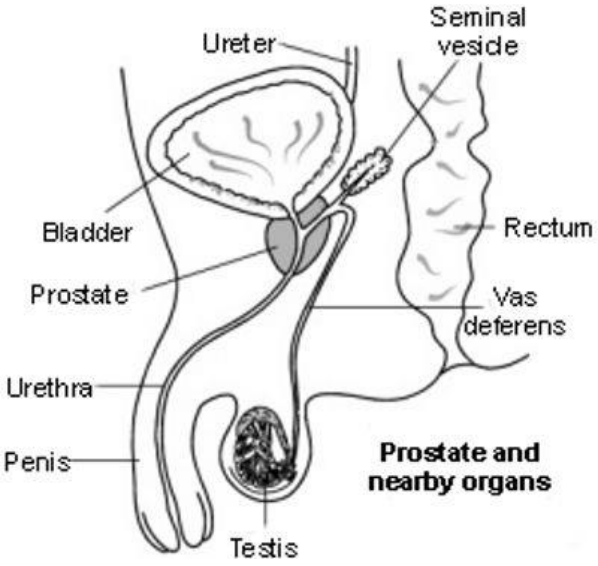
Information for patients, relatives and carers

Introduction

This leaflet provides information about a prostate treatment called NanoKnife focal irreversible electroporation (IRE) treatment of the prostate. It explains the benefits and risks of the procedure and what to expect when you come into hospital. We hope this leaflet will answer some of the questions you or those who care for you may have. It is not meant to replace the consultation between you and your medical team but aims to help you understand more about what is discussed.

What is the prostate?

The prostate is a gland which lies just below the bladder. In young men it is about the size of a walnut. Its size tends to increase with age. It surrounds the beginning of the tube that carries urine from the bladder to the tip of the penis. This is called the urethra.



The main function of the prostate is to supply fluid for the sperm during ejaculation. Prostate-specific antigen (PSA) is produced by the prostate gland. PSA is a substance released into the blood by the prostate and by prostate cancer cells.

Types of prostate cancer

Prostate cancer may be:

- localised (the cancer has not spread to other areas of the body and only affects the prostate)
- locally advanced (the cancer has spread outside the outer capsule of the prostate but not into the blood stream)
- metastatic (the cancer has moved outside the prostate and into the bloodstream and may affect other areas of the body)

Your surgeon will discuss with you what type of tumour you have and how likely it is to spread.

What is IRE for localised prostate cancer?

IRE treats prostate cancer focally using pulses of electricity which create tiny holes in cancer cells, causing them to die. The low energy direct current (LEDC) can be very finely pinpointed. This makes this method highly accurate and explains its commercial name: NanoKnife. The treatment takes about 1 to 2 hours.

During IRE, special needles or probes are passed into the prostate through the perineum. This is done in a similar manner to the prostate biopsy you had.

Your doctor will use ultrasound images of the prostate to confirm that the needles are in the correct position.

Our experience

Though IRE is a new procedure at Imperial, our team has experience of similar treatments.

IRE belongs to a group of prostate cancer treatments called focal therapies. These all use the same ultrasound technique to identify the area of the prostate that needs treatment. We have been providing them for thousands of patients here at Imperial College London and across the UK for over 15 years.

What are the benefits of IRE?

The benefits of IRE for localised prostate cancer include:

- there are no cuts (incisions). It is minimally invasive procedure
- it preserves sensitive structures (like nerves) around the treatment zone. This contributes to a low rate of side-effects
- short hospital stay – in most cases, men go home on the same day as treatment
- rapid recovery once you’re home. This means you can return to normal life quickly

- men treated with IRE undergo careful follow-up with PSA blood tests, MRI scans and sometimes prostate biopsy. (This is the same with any focal treatment)
- We can repeat IRE if we detect further prostate cancer in follow-up (if the cancer is suitable). Or men can choose a different prostate cancer treatment.men who need another cancer treatment after IRE may be suitable for radiotherapy, keyhole surgery to remove the prostate (prostatectomy) or drug treatment

IRE research

IRE is a newer treatment for prostate cancer. So, we do not yet have the data to tell us how effective it is at controlling cancer in the long term.

Researchers published the largest study so far in 2019. This showed:

- 5 in every 100 (5%) men treated with IRE needed a different prostate cancer treatment 3 years later. (This could be surgery to remove the prostate or radiotherapy)
- 10 in 100 (10%) of those treated underwent a second IRE treatment during those 3 years

IRE is being offered at Imperial as a normal NHS treatment, not as part of a clinical trial. However, we are going to analyse our IRE prostate cancer treatment and publish the anonymised results. We want to help doctors and patients understand more about IRE. This is in line with NICE guidance on IRE.

What are the risks of IRE?

The risks and benefits of any procedure are different for everyone. Your doctor will explain the risks that may affect you. Please feel free to ask your doctor or nurse specialist any questions you may have.

The most common risks of side effects are listed below. The chances of them happening are in brackets, where relevant:

Problems that may happen straight away:

- a small number of men have difficulty in passing urine after the treatment. So, patients have a tube (catheter) inserted at the time of the procedure to help with this. This is often left in for a week or so to allow swelling to settle
- some men will notice swelling of their penis or scrotum. This may happen in the first or second week after the procedure. This is temporary and will usually get better within a few months
- blood in the urine, semen and from the back passage can occur but will settle down after a few days. The blood in the semen can sometimes last weeks or even a few months. This should not cause any harm.
- a few men (3 or 4 in a hundred) may get an infection in the urinary system following treatment with IRE. This will usually settle with some antibiotic tablets

Problems that may happen later:

- problems getting or keeping an erection (erectile dysfunction) is possible. The nerves involved in creating an erection lie just behind the prostate gland and could be affected during the IRE procedure. This occurs in around 1 in 10 (10%) of patients and tends to recover over a year
- a dry orgasm or retrograde ejaculation (this is when the penis does not release semen at sexual climax) can develop in about 20 out of 100 (20%) patients. This is due to the scar in the treated area, especially if more extensive treatments are used
- leakage of urine (urine incontinence) can occur after treatment. This is very rarely permanent. Some men do wear pads to protect their underwear for a few days following the procedure. If this leakage carries on, we can teach pelvic floor exercises that will help your urinary control. In large studies, almost all men (99%) were pad free (continent) a year after IRE
- fistula. This is an abnormal connection between the prostate and the back passage (rectum). It can happen very rarely after most of the prostate cancer treatments. It may need require bowel surgery and a bowel bag on the tummy (stoma) to put right. It is extremely rare after IRE, affecting 1 man in 500 or less.

Consent

We involve you in all the decisions about your care and treatment. If you decide to go ahead with high-intensity focused ultrasound (HIFU) treatment, by law we must ask you to sign a consent form beforehand. This confirms that you agree to have the procedure and understand what it involves. Staff will explain all the risks, benefits and alternatives before they ask you to sign a consent form. If you are unsure about any aspect of your proposed treatment, please do not hesitate to speak with a senior member of staff.

How should I prepare for IRE treatment?

We will give you an appointment to meet with a pre-assessment nurse before your operation. At this pre-assessment we will let you know:

- what you should bring with you on the day of the operation
- whether to continue taking your medications as normal
- what time to arrive on the day
- when you should stop eating and drinking before you arrive

What happens on the day of the IRE procedure?

1. On the day, we will give you an enema to clear your back passage. This involves putting liquid in your back passage to empty it. This allows us to get clearer ultrasound pictures during the IRE treatment itself.
2. We will insert a tube that drains urine from the bladder (urinary catheter). This is normally placed through the urethra. It can feel uncomfortable and unusual to pass urine through and can cause your bladder to feel like it is full. (See below for suprapubic catheter)

3. The anaesthetist will explain the anaesthetic and ensure it is appropriate and safe. You will usually have a general anaesthetic.

What happens during the IRE procedure?

1. During IRE, special needles or probes are passed through the skin in front of the back passage (anus) and behind the scrotum (this area is called the perineum). The needles are placed into the prostate. Typically, 3 to 4 needles are placed, with a maximum of 6.
2. The surgeon uses ultrasound images of the prostate to confirm that the needles are in the correct position.
3. Depending on the distance between the needles, voltages of up to 3000V will be applied in very short pulses (90 microseconds). These pulses will create small holes in the cellular membrane of the cells within the targeted area. This causes the cells to die. The dead cells will be removed from the area by the body's own cleaning system called the macrophages.
4. Once the desired set of pulses is given between each needle pair, the needles will be removed.
5. You will be brought to the recovery unit.

If you need a suprapubic catheter

Usually before the procedure, a catheter will be placed in the penis for urine drainage. Rarely, this is not possible. In these cases, instead of going in the penis, the flexible tube is inserted into the bladder through a 1cm cut in the tummy, a few inches below the belly button. This is called a suprapubic catheter.

A telescope passed through the penis, called a cystoscope, is used to guide this. Insertion of a suprapubic catheter carries additional but very low risks of damaging the structures around the bladder.

This catheter will be left in place for a few days. On rare occasions, depending on the location of the tumour inside the prostate and the size, the catheter might be left in place for longer. Your doctor will inform you about this at the pre-surgical meetings.

What should I expect after the procedure?

You will be discharged home – with your escort.

A contact number will be given if you have any problems at home.

Most people recover from the IRE treatment within one to two weeks. In the days after the operation, you will probably feel more tired than usual. This is normally because of the anaesthetic. Remember to:

- drink plenty of fluid every day, around 1.5 to 2 litres. This will prevent you from becoming dehydrated and make urine infection less likely.
- avoid constipation as this leads to straining. To help with this you will be given gentle laxative syrup when you leave the hospital.

- keep the IRE needle puncture sites clean and dry. These will be in the skin in front of your back passage, called the perineum. You should not need any dressings once you leave the hospital.
- **pain** – it is normal to expect some discomfort after your IRE treatment particularly in and the area where the needles were inserted (the perineum). You will be given some pain killers when you leave hospital and you can get more from your GP if you need to.
- **bleeding** – occasionally, there may be slight bleeding from the area where the IRE needles were inserted (perineum). If this happens, you can apply a dry dressing.
- **bruising and swelling of scrotum** – you may develop some bruising in the area where the IRE needles were inserted (perineum). You may also get some swelling of your scrotum after the procedure. Both will settle without any treatment over a couple of months

Catheter care

- if possible, bath or shower daily. Otherwise wash the skin around the catheter once a day
- always wash your hands with soap and water before and after handling any part of the catheter
- if you have a urethral catheter, make sure you clean around where the catheter enters the penis. Clean the catheter itself using downward strokes away from the catheter. This should be done morning and night and after emptying your bowels
- if you have a urethral catheter, and you are uncircumcised, pay attention to washing under the foreskin. After washing be sure to replace the foreskin in its usual position
- when emptying your catheter, make sure that the end of the bag does not touch the toilet bowl or seat
- for the first 24 hours you should allow your catheter to drain freely into the catheter bag (leg bag). At night you may choose to attach it to a larger night bag
- after 24 to 48 hours, disconnect the bag from the catheter and attach a catheter valve. Your ward nurse may have already attached this, in which case, remove the catheter bag from the valve
- when the valve is switched off (that is, in the up position) your bladder will fill with urine. Once you feel the need to pass urine, open the tap, empty the urine down the toilet then close the tap again.
- always change your leg bag or catheter valve every 7 days. Do it sooner if they become soiled
- if you use a night bag, simply connect directly to your leg bag or catheter valve, as this will help protect you from infection
- before you go to sleep, ensure the catheter tap or valve is open, the drainage tap on the night bag is closed and that urine is draining

- dispose of the catheter bags by emptying urine into the toilet and putting the bag in household rubbish

Common problems you may experience with the catheter

- **urine infection** – while you have a catheter in place it is usual to have a harmless increase in the number of bacteria in your urine. This does not need treatment.

  However, if you experience one or more of the following new symptoms you should contact your GP: new lower back pain, high temperature and feeling generally unwell, cloudy offensive urine, worsening bladder pain or spasm

- **bladder spasms** – you may feel this as a strong or urgent sensation of the need to pass urine before the bladder is full. See 'How to deal with bladder spasms'

- **blood in your urine** – this is common after IRE treatment and may continue for up to 2 months. It is not a cause for concern unless you have a high temperature or fever, or if the bleeding is persistent or heavy. If you are concerned, please contact your GP or specialist nurse.

- **debris or sediment in the urine** – you may see some tissue, debris or sediment in your urine. This is common after IRE treatment. You should aim to drink 1.5 to 2 litres daily. This will encourage catheter drainage and should prevent your catheter from blocking.

- **urine leakage** – this may occur from around the catheter site or the urethra (water pipe). If this occurs you should check that your catheter is not blocked or release your catheter valve to empty the bladder. If leakage happens at the same time as you have a strong sensation of urgency, you may be having bladder spasms

- **catheter blockage** – this can be partial or total. If you think your catheter is blocked, you should check it is not kinked or twisted. Try changing your position. If still no urine drains, or you experience abdominal discomfort your catheter may need to be changed. You should seek immediate medical attention with your GP or local accident and emergency department.

Understanding bladder spasms

Having a urinary catheter in place can sometimes cause 'bladder spasms'. You may feel this as a strong or urgent sensation of the need to pass urine before the bladder is full.

This happens because both the catheter and the catheter balloon (which holds the catheter in place) irritate the bladder. Occasionally you may experience leakage of urine when you have a bladder spasm. This is because the spasm can cause a strong contraction of the bladder muscle. This in turn can force urine out in an uncontrolled way. The urine leakage may be around the catheter or catheter entry site, or via the urethra.

Sometimes the spasm may give rise to a sensation of discomfort or pain in the tip of the penis, particularly after urinating. (This sensation can also occur at the end of emptying the bladder via the catheter valve.)

Not all men will experience bladder spasms and severity of these can vary. It is important to remember that this will settle once the catheter is removed. In the meantime, you may find it

helpful to try not to force urine out when you have a spasm but rather try to relax and focus on deep breathing until the spasm passes.

If the bladder spasms are frequent and very troublesome then contact your GP practice or specialist nurse for further advice. There are medications to help with this. It may also be helpful to check that you do not have a urine infection if the spasms are very severe.

Having your catheter removed

Before you go home after your IRE procedure, you will be given an appointment at the 'trial without catheter clinic' or 'TWOC' at Imperial. This is where we will remove the catheter and assess your bladder emptying.

Expect to be in the department for around 3 to 4 hours. This will allow time for the catheter to be removed and for an assessment to be made that you are able to empty the bladder.

If you want to have the catheter removed near where you live, please contact your local clinical nurse specialist or your GP. They can work with local services to arrange this. If you can, arrange this well before your IRE treatment. Not all district or practice nurses are happy to manage the catheter removal. Some hospital departments may also decline.

If you are not having the catheter removed locally you will automatically be given a TWOC clinic appointment at Imperial.

You may experience discomfort or stinging when you start to pass urine normally. This will subside. Make sure you continue to drink 1.5 to 2 litres of fluid per day.

How will I be monitored in the future?

After treatment, it is important that you are monitored for a minimum of 10 years by your GP and hospital. Although most men can expect a cure from this treatment, some cancer cells may remain, or the cancer may come back (recur).

You will need regular check-ups and PSA blood tests after prostate cancer treatment. Usually, your PSA will be tested at the following frequency:

- every three months for the first year
- every six months for the next two years
- once a year after that

Your GP will conduct your PSA monitoring and will update us with your readings.

An MRI scan is done after one year and may sometimes be repeated.

At your follow-up appointments we will also ask you about any urine or erection problems you may have. We will offer support or treatment, as necessary. If you experience any difficulties with your erections or urine symptoms, please speak to your doctor or contact your clinical nurse specialist (CNS).

Contact

Imperial College Healthcare NHS Trust has a Macmillan navigator service for access to your CNS and other members of the clinical team.

Navigators can also help with queries and provide a range of other information, help and support relating to your care. The service is available Monday to Friday. 08.00 to 18.00 and 09.00 to 17.00 at weekends. Telephone: 020 3313 0303

Where can I get more information?

The following sources of information and support may be of help with your diagnosis and treatment.

Macmillan Cancer Information and Support Service at Charing Cross and Hammersmith hospitals. The information centre at Charing Cross Hospital and the infopod at Hammersmith Hospital provide emotional and practical support, as well as signposting advice to anyone

affected by cancer. These drop-in services are set in friendly, non-clinical environments in which people affected by cancer can discuss private and emotional needs with dedicated Macmillan information professionals.

The information centre is located on the ground floor of Charing Cross Hospital. Telephone: 020 3313 0171

The infopod is located on the ground floor of the Gary Weston Centre at Hammersmith Hospital. Telephone: 020 3313 4248

Maggie's Cancer Caring Centre

Maggie's is a cancer charity that provides emotional, practical and social support that people with cancer may need. This drop-in centre combines striking buildings, calming spaces, professional experts offering support, and the ability to talk and share experiences with a community of people who have been through similar experiences. Maggie's West London is located in the grounds of Charing Cross Hospital but please note it is independent of our hospital. For more information, please call 020 7386 1750.

Macmillan Cancer Support Helpline

This is a free line of support and information for people affected by cancer, who have questions about cancer, need support or just someone to talk to.
Telephone: 0808 808 0000 www.macmillan.org.uk

Prostate Cancer UK

Telephone: 0800 074 8383 www.prostatecanceruk.org

How do I make a comment about my visit?

We aim to provide the best possible service and staff will be happy to answer any of the questions you may have. If you have any **suggestions** or **comments** about your visit, please either speak to a member of staff or contact the patient advice and liaison service (**PALS**) on **020 3312 7777** (10.00 – 16.00, Monday to Friday). You can also email PALS at imperial.pals@nhs.net The PALS team will listen to your concerns, suggestions or queries and is often able to help solve problems on your behalf.

Alternatively, you may wish to complain by contacting our complaints department:

Complaints department, fourth floor, Salton House, St Mary's Hospital, Praed Street
London W2 1NY

Email: ICHC-tr.Complaints@nhs.net

Telephone: **020 3312 1337 / 1349**

Alternative formats

This leaflet can be provided on request in large print or easy read, as a sound recording, in Braille or in alternative languages. Please email the communications team: imperial.communications@nhs.net

Wi-fi

Wi-fi is available at our Trust. For more information visit our website: www.imperial.nhs.uk

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