



INTRAVESICAL IMMUNOTHERAPY WITH BCG

Procedure Specific Information

What is the evidence base for this information?

This publication includes advice from consensus panels, the British Association of Urological Surgeons, the Department of Health and evidence-based sources. It is, therefore, a reflection of best urological practice in the UK. It is intended to supplement any advice you may already have been given by your GP or other healthcare professionals. Alternative treatments are outlined below and can be discussed in more detail with your Urologist or Specialist Nurse.



What does the procedure involve?

Instillation of BCG into the bladder for aggressive or recurrent superficial cancer of the bladder

What are the alternatives to this procedure?

Repeated cystoscopy, radiotherapy, surgical removal of the bladder with urinary diversion or bladder reconstruction, systemic chemotherapy

What should I expect before the procedure?

Your Consultant Urologist has referred you for treatment of your superficial bladder cancer. Superficial bladder cancer affects the inner surface of the bladder only but has the ability to progress to more aggressive disease.

The aim of the treatment, therefore, is to stop or slow down re-growth by instilling a drug into the bladder; this is called intravesical immunotherapy. The treatment recommended for you is BCG. BCG is a commonly-used vaccine against tuberculosis (TB) and contains a bacterium from the same family as the TB bacterium which has been altered (attenuated) to reduce the risk of infection whilst retaining the ability to produce the immune reaction needed for its beneficial effect. It has been shown that putting liquid containing BCG vaccine into the bladder is an effective treatment for bladder cancer.

Like all powerful treatments, it comes with some possible side-effects (see below) and the risk of these should be considered against the risk of the bladder cancer for which the treatment is being given.



There is also some evidence that BCG treatment can interact with influenza vaccine; for this reason, it is recommended that you do not undergo vaccination against influenza within 6 weeks of having an instillation of BCG.

The first course is called the Induction Course and lasts for 6 weeks. Following completion of this, you will enter a program of treatment lasting approximately 3 years which includes several doses of BCG, each one preceded by a flexible cystoscopy. The main reasons for patients failing to complete the full course are side-effects (see below) and/or disease progression/

You should limit your fluid input for 6 hours before each treatment.

Your first treatment will take up to 3 hours and, depending on how well you tolerate the first treatment, future visits will take approximately 30 minutes.

On arrival in the clinic, you will be asked to pass urine which will be tested to ensure that you do not have an infection in the urine. If you do, your treatment will need to be postponed for one week while you are treated with antibiotics.

Please be sure to inform your surgeon in advance of your surgery if you have any of the following:

- an artificial heart valve
- a coronary artery stent
- a heart pacemaker or defibrillator
- an artificial joint
- an artificial blood vessel graft
- a neurosurgical shunt
- any other implanted foreign body
- a regular prescription for Warfarin, Aspirin or Clopidogrel (Plavix®)
- a previous or current MRSA infection
- a high risk of variant-CJD (if you have received a corneal transplant, a neurosurgical dural transplant or previous injections of human-derived growth hormone)

At some stage during the admission process, you will be asked to sign the second part of the consent form giving permission for your operation to take place, showing you understand what is to be done and confirming that you wish to proceed. Make sure that you are given the opportunity to discuss any concerns and to ask any questions you may still have before signing the form.



Fact File 1 • The NHS Constitution Same-Sex Accommodation

As a result of the new NHS constitution, the NHS is committed to providing same-sex accommodation in hospitals by April 2010. This is because feedback from patients has shown that being in mixed-sex accommodation can compromise their privacy. The NHS pledges that:

- sleeping and washing areas for men and women will be provided
- the facilities will be easy to get to and not too far from patients' beds

To help accomplish this, the Department of Health has announced specific measures designed to "all but eliminate mixed-sex accommodation" by 2010. These include:

- more money for improvements in hospital accommodation
- providing help and information to hospital staff, patients and the public
- sending improvement teams to hospitals that need extra support
- introducing measures so that the Department can see how hospitals are progressing

What happens during the procedure?

A fine plastic tube (called a catheter) will be passed into the bladder and the medication (approximately half a cup of fluid) will be given through it. The catheter will then be removed. You will be asked not to pass urine for two hours to allow the medication to treat the bladder lining.

On your first visit, you will be asked to stay in the clinic for the duration of the treatment and you will be asked to pass urine before you go home. For the remaining treatments, if you live within 20 minutes of the hospital and have your own transport, you may be allowed to go home with the medication in your bladder and pass urine after two hours.

What happens immediately after the procedure?

In general terms, you should expect to be told how the procedure went and you should:

- ask if what was planned to be done was achieved
- let the medical staff know if you are in any discomfort
- ask what you can and cannot do
- feel free to ask any questions or discuss any concerns with the ward staff and members of the surgical team
- ensure that you are clear about what has been done and what is the next move



Once the treatment has been completed, you will be able to go home.

Urine passed within the first 6 hours after you have been treated should be disinfected by pouring a quantity of undiluted household bleach (equal to the amount of urine passed) into the toilet; this should then be left for 15 minutes before flushing the toilet.

You should drink plenty of fluids (2-3 litres) for the few days after the treatment. Some patients find that, for a few days after BCG treatment, a glass of cranberry juice daily eases any bladder symptoms; cranberry juice, however, should not be used if you are taking Warfarin.

Are there any side-effects?

Most procedures have a potential for side-effects. You should be reassured that, although all these complications are well-recognised, the majority of patients do not suffer any problems after a urological procedure.

Common (greater than 1 in 10)

- Urinary tract infection requiring postponement of the next dose of BCG
- Some bladder discomfort after treatment
- Flu-like symptoms which can persist for 2-3 days
- Frequency and urgency of urination which can persist for 2-3 days
- Failure to complete the course of treatment due to bladder discomfort
- Blood in the urine
- Debris in the urine

Occasional (between 1 in 10 and 1 in 50)

- Stricture of the urethra (water pipe) following repeated use of a catheter
- A number of inflammatory reactions which can affect various parts of the body (the liver, joints and the back of the eye)

Rare (less than 1 in 50)

- Persistent or severe pain after treatment, sometimes requiring removal of the bladder
- Generalised and potentially serious infection with the BCG bacteria requiring treatment in hospital with powerful antibiotics. This is not TB and there is no risk of catching TB from the treatment

Hospital-acquired infection

- Colonisation with MRSA (0.9% - 1 in 110)
- Clostridium difficile bowel infection (0.2% - 1 in 500)
- MRSA bloodstream infection (0.08% - 1 in 1250)

The rates for hospital-acquired infection may be greater in high-risk patients e.g. with long-term drainage tubes, after removal of the bladder for cancer, after previous infections, after prolonged hospitalisation or after multiple admissions.



What should I expect when I get home?

By the time of your discharge from hospital, you should:

- be given advice about your recovery at home
- ask when to resume normal activities such as work, exercise, driving, housework and sexual intimacy
- ask for a contact number if you have any concerns once you return home
- ask when your follow-up will be and who will do this (the hospital or your GP)
- ensure that you know when you will be told the results of any tests done on tissues or organs which have been removed



If you think you have a urine infection (i.e. pain on passing urine, frequency or foul-smelling urine) or If you develop a high temperature with backache, it is important to contact your GP and get treatment with antibiotics.

What else should I look out for?

Because this treatment is put directly into the bladder and not into the blood stream, you will not experience the side-effects often associated with other cancer drug treatments.

Are there any other important points?

You should wash your hands and genitals after you have passed urine and it is advisable to bring a wash bag with you to hospital when you come for the treatment.

Men should pass urine sitting down on the first occasion after the instillation but, thereafter, may pass urine in the normal fashion (standing).

You are advised not to have sexual intercourse for at least 24 hours after the treatment as this can cause some discomfort. For the duration of the treatment course, and for one week after the course, you should use a condom during sexual intercourse.

If you are a smoker, you should be aware that smoking seems to encourage recurrence of bladder cancer.

Driving after surgery

It is your responsibility to ensure that you are fit to drive following your surgery. You do not normally need to notify the DVLA unless you have a medical condition that will last for longer than 3 months after your surgery and may affect your ability to drive. You should, however, check with your insurance company before returning to driving. Your doctors will be happy to provide you with advice on request.

Is there any research being carried out in this area?



Before your operation, your surgeon or Specialist Nurse will inform you about any relevant research studies taking place, and, in particular, if any surgically-removed tissue may be stored for future study. If this is the case, you will be asked if you wish to participate and, if you agree, to sign a special form to consent to this.

All surgical procedures, even those not currently the subject of active research, are subjected to rigorous clinical audit so that we can analyse our results and compare them with those of other surgeons. In this way, we can learn how to improve our techniques and our results; this means that our patients will get the best treatment available.

Who can I contact for more help or information?

For further information on the internet, here are some useful sites to explore:

[Best Health](#) (prepared by the British Medical Association)

[NHS Clinical Knowledge Summaries](#) (formerly known as Prodigy)

[NHS Direct](#)

[Patient UK](#)

[Royal College of Anaesthetists](#) (for information about anaesthetics)

[Royal College of Surgeons](#) (patient information section)

What should I do with this information?

Thank you for taking the trouble to read this publication. If you wish to sign it and retain a copy for your own records, please do so below.

If you would like a copy of this publication to be filed in your hospital records for future reference, please let your Urologist or Specialist Nurse know. However, if you do agree to proceed with the scheduled procedure, you will be asked to sign a separate consent form which will be filed in your hospital record. You will, if you wish, be provided with a copy of this consent form.

I have read this publication and I accept the information it provides.

Signature..... Date.....



How can I get information in alternative formats?

Please ask your local NHS Trust or PALS network if you require this information in other languages, large print, Braille or audio format.



Most hospitals are smoke-free. Smoking increases the severity of some urological conditions and increases the risk of post-operative complications. For advice on quitting, contact your GP or the **NHS Smoking Helpline** free on **0800 169 0 169**

Disclaimer

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Fact File 2 • The NHS Constitution **Patients' Rights & Responsibilities**

The constitution, as a result of extensive discussions with staff and the public, sets out new rights for patients which will help improve their experience within the NHS. These new rights include:

- a right to choice and a right to information that will help them make that choice
- a right to drugs and treatments approved by NICE when it is considered clinically appropriate
- a right to certain services such as an NHS dentist and access to recommended vaccinations
- the right that any official complaint will be properly and efficiently investigated, and that they be told the outcome of the investigations
- the right to compensation and an apology if they have been harmed by poor treatment

The constitution also lists patient responsibilities, including:

- providing accurate information about their health
- taking positive action to keep themselves and their family healthy
- trying to keep appointments
- treating NHS staff and other patients with respect
- following the course of treatment that they are given
- giving feedback, both positive and negative, after treatment