

BCG INSTILLATION into the BLADDER for IMMUNOTHERAPY Information about your procedure from The British Association of Urological Surgeons (BAUS)

This leaflet contains evidence-based information about your proposed urological procedure. We have consulted specialist surgeons during its preparation, so that it represents best practice in UK urology You should use it in addition to any advice already given to you.

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KEY POINTS

- This involves having a catheter (plastic tube) passed into your bladder to instil an anti-cancer drug called BCG
- BCG is a vaccine that is used against tuberculosis; it contains live bacteria which have been attenuated (altered) to reduce the risk of infection. It stimulates immune cells in the bladder to kill cancer cells
- It is used for non-muscle invasive cancers, which grow in the thin layer of cells lining the bladder but do not extend into the muscle of the bladder wall
- Treatment involves weekly instillations for 6 weeks (induction treatment), followed by shorter maintenance treatments at 3-6 monthly intervals for up to three years
- Treatment reduces the chance of your bladder cancer returning and progressing
- Bladder tumours can recur during or after treatment, so follow-up bladder examinations (cystoscopies) are needed
- Like all powerful treatments, it comes with some significant sideeffects which you should balance against the risks of the bladder cancer itself

What does this procedure involve?

Instillation of an immunotherapy drug (BCG) into the bladder for aggressive or frequently recurring non-muscle invasive cancer of the bladder.

To instil the BCG, we need to put a catheter (plastic tube) through your urethra (waterpipe) into your bladder (pictured below).

What are the alternatives?

- **Repeated cystoscopy** with electrical or laser cauterisation of any tumours found
- Intravesical chemotherapy instillation of an anti-cancer drug (Mitomycin C or Epirubicin) into the bladder
- Surgical removal of the bladder (radical cystectomy) with urinary diversion or bladder reconstruction

What happens on the day of the procedure?

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

On arrival in the clinic, we will ask you to pass urine and we will test it for infection. If testing suggests an infection, we will send a sample to the laboratory and, depending on your symptoms, may postpone your BCG treatment whilst you take a course of antibiotics.

If your urine is clear, your urologist (or a member of their team) will briefly review your history and medications, and will discuss the procedure again with you to confirm your consent.

You should allow up to three hours for your first treatment but, after that, your treatments should take approximately 30 minutes.

Details of the procedure

- we clean your genital area with an antiseptic solution and squirt an antiseptic gel (containing local anaesthetic) into your urethra (water pipe)
- we pass a small catheter into your bladder (pictured right)
- we instil approximately half a cupful of the BCG preparation through the catheter



- we remove the catheter from your bladder
- we ask that you try not to pass urine for the next two hours, to allow the medication to treat the whole bladder lining
- on your first visit, we normally keep you in the clinic until you have passed urine but, for any remaining treatments, you may be allowed to leave after two hours and pass urine at home
- for up to 6 hours after the treatment, you should urinate while sitting to minimise the risk of splashing urine which contains live bacteria
- you should pour undiluted household bleach (equal to the amount of urine you pass) into your toilet, and leave this for 15 minutes before flushing the toilet
- you should drink plenty of fluids (two to three litres) for the first few days after the treatment

The first course of weekly treatments is called the **induction course** and lasts for six weeks. You will then start a program of **maintenance treatment** lasting for one year. This will involve a series of 3-weekly instillations every three, six and 12 months with a cystoscopy before each one. After this, you may be advised to have further "top-up" treatments every six months for up to three years. However, due to limited supplies of BCG, some suitable patients may received a slightly reduced schedule of instillations.

The main reasons for patients failing to complete the full course are sideeffects (see below) or finding that the cancer has regrown in the bladder.

Are there any after-effects?

The possible after-effects and your risk of getting them are shown below. Some are self-limiting or reversible, but others are not. We have not listed very rare after-effects (occurring in less than 1 in 250 patients) individually. The impact of these after-effects can vary a lot from patient to patient; you should ask your surgeon's advice about the risks and their impact on you as an individual:

After-effect	Risk
Infection in your urine (this usually means that the next dose of BCG needs to be postponed)	Between 1 in 2 & 1 in 10 patients

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Some bladder discomfort	Between 1 in 2 & 1 in 10 patients
Flu-like symptoms which can last for two to three days	Between 1 in 2 & 1 in 10 patients
Urgently wanting to pass urine and needing to pass it more frequently (lasting for up to three days)	Between 1 in 2 & 1 in 10 patients
Failure to complete the course due to discomfort in your bladder at the time of treatment	Between 1 in 2 & 1 in 10 patients
Blood in your urine	Between 1 in 2 & 1 in 10 patients
Debris in your urine	Between 1 in 2 & 1 in 10 patients
Stricture (narrowing) of the urethra (waterpipe) following repeated use of a catheter	Between 1 in 10 & 1 in 50 patients
Inflammation which can affect various parts of the body (liver, joints and the back of your eye)	Between 1 in 10 & 1 in 50 patients
Persistent or severe pain after treatment (sometimes leading to removal of the bladder)	Between 1 in 50 & 1 in 250 patients
Generalised (and serious) infection with BCG bacteria needing treatment in hospital with powerful antibiotics. This is not TB & there is no risk of catching TB from the treatment	Between 1 in 50 & 1 in 250 patients

What can I expect when I get home?

• We will send a copy of your treatment details to your GP

- any antibiotics or other tablets you may need will be arranged & dispensed, either from the hospital pharmacy or by your GP
- you should always wash your hands and your genitals every time you pass urine over the next few days (we suggest that you bring a wash bag with you every time you come to the hospital for treatment)
- it is best not to have sex for at least 24 hours after each treatment because this can be uncomfortable
- during a treatment course, and for one week afterwards, you should use a condom during sex
- if you are a smoker, you should try to stop because smoking can encourage the return of bladder cancer (see below)

If you think you have a urine infection (pain when passing urine, passing urine more frequently 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.

General information about surgical procedures

Before your procedure

Please tell a member of the medical team if you have:

- an implanted foreign body (stent, joint replacement, pacemaker, heart valve, blood vessel graft);
- a regular prescription for a blood thinning agent (e.g. warfarin, aspirin, clopidogrel, rivaroxaban, dabigatran);
- a present or previous MRSA infection; or
- a high risk of variant-CJD (e.g. if you have had a corneal transplant, a neurosurgical dural transplant or human growth hormone treatment).

Questions you may wish to ask

If you wish to learn more about what will happen, you can find a list of suggested questions called <u>"Having An Operation"</u> on the website of the Royal College of Surgeons of England. You may also wish to ask your surgeon for his/her personal results and experience with this procedure.

Before you go home

You will be given advice about what to look out for when you get home. Your surgeon or nurse will also give you details of who to contact, and how to contact them, in the event of problems.

Smoking and surgery

Since you are only having a local anaesthetic, stopping smoking will have no

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effect on the safety of the procedure itself. Smoking can, however, cause cancers of the urinary tract, and can encourage existing cancers to recur or progress. We strongly advise patients with bladder cancer to stop smoking.

For advice on stopping, you can:

- contact your GP;
- access your local <u>NHS Smoking Help Online</u>; or
- ring the Smoke-Free National Helpline on **0300 123 1044**.

Driving after any procedure

It is your responsibility to make sure you are fit to drive even after a minor surgical procedure. You only need to <u>contact the DVLA</u> if your ability to drive is likely to be affected for more than three months. If it is, you should check with your insurance company before driving again.

What should I do with this information?

Thank you for taking the time & trouble to read this information. Please let your urologist (or specialist nurse) know if you would like to have a copy for your own records. If you wish, the medical or nursing staff can also arrange to file a copy in your hospital notes.

What sources have we used to prepare this leaflet?

This leaflet uses information from consensus panels and other evidencebased sources including:

- the <u>Department of Health (England);</u>
- the <u>Cochrane Collaboration</u>; and
- the National Institute for Health and Care Excellence (NICE).

It also follows style guidelines from:

- the Royal National Institute for Blind People (RNIB);
- the Information Standard;
- the Patient Information Forum; and
- the Plain English Campaign.

DISCLAIMER

Whilst we have made every effort to give accurate information, there may still be errors or omissions in this leaflet. BAUS cannot accept responsibility for any loss from action taken (or not taken) as a result

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PLEASE NOTE: the staff at BAUS are not medically trained, and are unable to answer questions about the information provided in this leaflet. If you have any questions, you should contact your Urologist, Specialist Nurse or GP in the first instance.