University College Hospital at Westmoreland Street

Intravesical immunotherapy with BCG

Urology Directorate
If you require a large print, audio or translated version of this leaflet, please contact us on 0845 155 5000 ext 79280. We will try our best to meet your needs.

Contents
Introduction 5
What does intravesical treatment mean? 5
What is a cancerous bladder tumour? 5
How can intravesical BCG treatment help? 7
What are the potential side effects of BCG treatment? 7
Are there other important points? 9
What will happen if I choose not to have BCG treatment? 10
What alternatives are available? 10
How should I prepare for the treatment? 10
What happens during BCG treatment? 11
What should I expect after BCG treatment? 11
What is the treatment regime? 12
References 13
Contact details 13
Where can I get more information? 13
How to find us 14
Space for notes and questions 15
Introduction
This booklet will give you an overview of BCG (Bacillus Calmette-Guérin) therapy, how it is given and side effects it may cause. Please read it carefully as it contains information that will help you to minimise any possible problems the treatment may cause. If you have any concerns or would like further information please do not hesitate to contact one of the urology team on the numbers at the back of this leaflet.

What does intravesical treatment mean?
This involves putting medicine directly into the bladder to treat a condition. This medicine is BCG (Bacillus Calmette-Guérin). You may have heard of BCG. This is the vaccine that is given to stop a person from getting tuberculosis. In this case, it is used as immunotherapy to slow down or stop a cancerous bladder tumour from growing inside the bladder.

What is a cancerous bladder tumour?
A tumour is an abnormal growth of the body’s tissue cells and can be classified as benign (not cancer) or malignant (cancer). Benign tumours do not invade healthy tissue or spread around the body, they are not cancers. Malignant tumours have the ability to invade healthy tissue and to spread to other areas of the body.

The bladder is a hollow, muscular, balloon-like organ. It is in your lower pelvis and connected to your kidneys by two tubes called ureters. Urine passes down these tubes and is collected and stored in the bladder. Urine is passed out of the bladder through a tube like structure called the urethra.

In women this is a short tube which opens up in front of the vagina while in men it is much longer and passes through the prostate and penis.

The bladder is lined with a urine proof membrane called the urothelium which is made up of cells called transitional cells.
Most cancers in the bladder start in this membrane layer and are called transitional bladder cancers. Other, rarer, types of bladder cancer are squamous cell cancer and adenocarcinoma. Squamous cell cancer starts from one of the types of cell in the bladder lining. Adenocarcinoma starts from glandular cells which produce mucus.

Some bladder cancers form warty outgrowths or mushroom-like growths on the inside lining of the bladder. These are called papillary cancers. They have a short stem attached to the lining of the bladder. Sometimes they go on to spread into the wall of the bladder.

If a bladder cancer only affects the inner lining of the bladder, it is known as a superficial cancer. If it has spread into the muscle wall of the bladder, it is called an invasive cancer.

Bladder cancer occurs most commonly in people between 50 and 70 years of age. It is the fourth most common cancer in men and eighth most common in women in the UK. You may also hear your cancer referred to as a neoplasm, growth, polyp or wart. If you are confused please feel free to ask a nurse or doctor to explain things to you.
How can intravesical BCG treatment help?
Your Consultant Urologist has referred you for treatment of your superficial bladder cancer with BCG. Superficial bladder cancer affects the inner surface of the bladder only but has the ability to progress to more invasive disease. The aim of the treatment is to reduce the tendency for new and more invasive tumours to develop in the future by instilling the BCG into the bladder.

BCG is a commonly-used vaccine against tuberculosis (TB) and contains bacteria from the same family as TB bacteria which have been altered to reduce the risk of infection whilst retaining the ability to stimulate the immune system sufficiently for its beneficial effect. It is not fully understood how BCG works but in general terms is believed that the treatment causes inflammation within your bladder which, in turn, activates your immune system to destroy cancer cells. The treatment is given directly into your bladder so it can coat the entire bladder lining and provide the maximum benefit.

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.

What are the potential side effects of BCG treatment?
While some side-effects can be unpleasant with BCG treatment, they are usually manageable and go away in the days following treatment. Others require specific treatment. Occasionally, it may not be possible for you to complete the course of treatment due to particular or severe side effects. Please talk to your nurse or doctor if you are worried about side-effects or feel they may prevent you from finishing the course.

Following treatment, if you experience the following symptoms you must contact your doctor or seek emergency help immediately (if attending the Accident and Emergency department, please bring this information with you to aid in your treatment):
• Any sign of an allergic reaction which includes difficulty in breathing, shortness of breath, wheezing, rash and/or swelling of the face.

• Any sign of a BCG infection which includes cough, high fever (temperature greater than 39.5 °C/103.1 °F) for more than 12 hours or a fever (temperature greater than 38.5 °C/101.3 °F) which lasts longer than two days.

Common (affecting more than one in 10 people) side effects:
• Urinary tract infection requiring postponement of the next dose of BCG.
• Some bladder discomfort and/or painful urination after treatment.
• Flu-like symptoms (chills, fever, headaches, muscle aches) which can persist for two to three days.
• Frequency and urgency of urination. This may persist for two to three days or sometimes longer. If these symptoms do not settle quickly, you should be tested for urinary infection. Urinary tract infection requires antibiotic treatment and postponement of the next dose of BCG.
• Blood in the urine.
• Debris in the urine

Occasional (affecting between one in 10 and one in 50 people) side effects:
• Inflammatory reactions can develop in various parts of the body (including testes, liver, joints and the back of the eye). You should report symptoms that could be related to these complications immediately, as they may need treatment.
• Narrowing of the urethra (water pipe) following repeated use of a catheter.
Rare (affecting less than one in 50 people) side effects:
• Persistent or severe bladder pain after treatment.
• Generalised and potentially serious infection with the BCG bacteria requiring antibiotic 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 to 1 per cent in 110 people).
• Clostridium difficile bowel infection (0.2 to 1 per cent in 500 people).
• MRSA bloodstream infection (0.08 to 1 per cent in 1250 people).

Are there other important points?
• You are advised not to have sexual intercourse for at least 24 hours after each treatment dose as this can cause discomfort. For the duration of the course of treatment and for one week after finishing the course, you should use a condom during sexual intercourse.
• If you are a smoker, you should be aware that smoking seems to encourage the recurrence of bladder cancer.
• It may be preferable to talk to your employer ahead of time to schedule time off work during your treatment days.
• It is not known what effects BCG has on pregnancy, therefore it is recommended that female patients use birth control for the duration of their treatment.
• Women should not breastfeed while receiving BCG treatment.
What will happen if I choose not to have BCG treatment?
Your consultant has recommended BCG treatment because of your symptoms and investigation findings. If you choose not to have this treatment your consultant will discuss any alternatives that may be suitable for your type of bladder cancer. However it is important to note that not having treatment could have serious consequences for your health.

What alternatives are available?
Your Urologist will have discussed alternative treatments options with you. They include repeated cystoscopy, radiotherapy, surgical removal of the bladder with urinary diversion or bladder reconstruction and intravesical chemotherapy. Such treatments may need to be reconsidered in the future, particularly if your cancer does not respond to the BCG treatment or recurs. Please do ask your nurse or doctor if you require further information about these alternatives.

How should I prepare for the treatment?
You should not drink for two hours before coming for treatment. This is so you are able to hold the BCG more easily inside your bladder and also to keep its concentration at an acceptable level.

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

Please advise your nurse or doctor of any medications you take regularly. Certain drugs—particularly immuno-suppressant’s and some antibiotics—can affect how the treatment works. If you are on antibiotic treatment please contact us to check if you can have the treatment. Some antibiotics cause the BCG to be less effective and we would recommend you finish your course and wait at least a week before starting or carrying on BCG treatment.
What happens during BCG treatment?
When you arrive for your treatment you will be asked to empty your bladder. If you have already started some treatment your nurse will discuss with you how you have been feeling since the last dose and whether you have experienced any side-effects (see above).

For the treatment you will then be asked to lay flat on a couch. Some lubricating gel will be placed in your urethra (water pipe) and a fine plastic tube (called a catheter) will be passed through the urethra and into the bladder. Any remaining urine will be drained and the BCG will then be instilled through the catheter (this is a liquid solution of about 50 ml).

Ideally you should hold the BCG solution in your bladder for two hours to allow the BCG bacteria to have the most beneficial effect.

Please note that we will not be able to administer the BCG if you have a lot of blood in your urine or there are any signs of a urinary tract infection.

What should I expect after BCG treatment?
Most patients will be able to travel home whilst the BCG solution is being held in their bladder. They will then pass the solution down the toilet at home after the two hours are up.

Urine passed within the first six 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. Men should sit down to pass urine on the first occasion after the instillation of treatment but may pass urine in the normal fashion (standing) thereafter.

You should drink plenty of fluids (two to three 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 as this can change how the warfarin works.

Taking medications such as paracetemol or aspirin can help you cope with any side-effects. Please always read the instructions for use.
What is the treatment regime?
Treatment regimes can vary slightly between hospitals but all follow established guidelines for treatment which are based on evidence from clinical trials. The course of treatment at UCLH is made up of two parts:

**Induction course**
- Once weekly instillations of BCG for six weeks.
- Following this, a six week break with no treatment (to allow the bladder to recover).
- A cystoscopy under a general anaesthetic is then performed (this will be planned in advance at the beginning of the induction course).
- As long as no recurrence of the bladder cancer is found on cystoscopy, a further cycle of three weekly instillations of BCG is given.

**Maintenance courses**
- These are necessary when there is no tumour recurrence in order to maintain the benefit of the induction courses.
- Weekly instillations of BCG for between one and three weeks (depending on the side-effects experienced) every six months.
- We aim to begin the first maintenance course of treatment at six months from the very beginning of the induction course.
- Up to six maintenance courses can be given, which can take up to three years overall.
- During the first two years of treatment between each maintenance course, two flexible (local anaesthetic) cystoscopies are performed to ensure the bladder is checked regularly for any sign of recurrence of the bladder cancer. After this time this is reduced to one cystoscopy in between treatments.

Our specialist urology nurses are responsible for organising your treatment regime. They will also administer the BCG in the outpatient clinic and provide a point of contact for you for ongoing support throughout your treatment (see contact details below). A cystoscopy under general anaesthetic will require a short stay in hospital (usually as a day case). A flexible cystoscopy is performed in the outpatient setting.
References
Developed using recommendations from British Association of Urological Surgeons Cambridge Laboratories

Contact details
University College Hospital at Westmoreland Street
Switchboard: 0845 155 5000 or 020 3456 7890
Website: www.uclh.nhs.uk

Richard Weston, Urology Nurse Practitioner
Mobile: 07711 113416
Email: Richard.Weston@uclh.nhs.uk

Rachel Leaver, Urology Lecturer Practitioner
Telephone: 020 3447 7903
Email: Rachel.Leaver@uclh.nhs.uk

Hazel McBain, Urology Research Nurse
Telephone: 07961 227106
Email: Hazel.Mcbain@uclh.nhs.uk

PA for Mr Feneley
Telephone: 020 3447 9194

Where can I get more information?

Macmillan Cancer Support
Website: www.macmillan.org.uk

NHS Clinical Knowledge Summaries
Website: www.cks.nhs.uk

NHS Direct
Telephone: 0845 46 47
Website: www.nhsdirect.nhs.uk

Patient UK
Website: www.patient.co.uk
How to find us

University College Hospital at Westmoreland Street
16 - 18 Westmoreland St, London, W1G 8PH

BCG clinic
Address: 2nd Floor, Macmillan Cancer Centre
           Huntley Street
           London, WC1E 6AG
Space for notes and questions