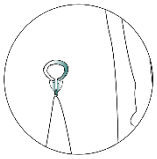
A urothelial bladder cancer clinical trial



Testing the role of DNA in the blood to guide immunotherapy after surgery for bladder cancer

BLC.6 | NCT05987241

What is the purpose of this trial?

The purpose of this study is to determine whether a blood test can help us make better decisions about who should get immunotherapy after surgery for bladder cancer and which immunotherapy treatment is best.

Why is this trial important?

The study will investigate a new test which can detect bladder cancer DNA in the blood. This is important because this test might indicate the presence of bladder cancer cells somewhere in the body, even if cancer can't be seen on a scan of the body.

For those with a positive blood test result, the study will investigate a new type of drug for the treatment of bladder cancer. This is important because there is some evidence that this new drug, in combination with the standard immunotherapy agent, may help slow the growth of bladder cancer, but it is not clear if it can offer better results than the standard treatment. For those with a negative blood test result, the study will investigate whether treatment with the standard immunotherapy agent is necessary.

Who can participate in this study?

This trial is for adults 18 years of age or older with a history of muscle-invasive urothelial bladder cancer.

This trial is for individuals who:

- Have had a radical cystectomy (removal of the bladder by surgery) between 3 and 12 weeks ago
- Have no evidence of residual (remaining) cancer following the procedure
- Are at high risk of recurrence (the cancer coming back), as indicated by your doctor
- Have tumour tissue available for testing

This trial is not for individuals who:

- Have received additional treatment for their cancer following their radical cystectomy (bladder cancer surgery)
- Have received prior treatment with immunotherapy drugs such as PD-1/PD-L1 or LAG-3 inhibitors
- Are pregnant or plan to become pregnant
- Have a history of heart or lung disorders
- Are on medications which reduce the immune system called immunosuppressive medications or anti-cancer drugs
- Require a treatment for kidney impairment called dialysis

SHARE THIS SUMMARY WITH YOUR HEALTH CARE TEAM
TO SEE IF THIS TRIAL IS A GOOD OPTION FOR YOU.

What are the risks?

If you choose to take part in this study, there is a risk that the use of immunotherapy treatment guided by the results of this new test may not be as good as the standard treatment. There is also a risk that you could have side effects from the new drug. Some of the most common side effects that the study doctors know about are: anemia (which may require blood transfusion), swelling of the lymph nodes, damage to the heart, and blurred vision. You will find details of all side effects in the consent document.

What can I expect?

If you choose to take part in this study, you will be entered into the trial and first have the new blood test. If the test results are positive for cancer cells, you will be randomly placed in one of two groups and you will receive either the standard drug commonly used to treat this disease, or the standard drug plus the new drug. If the test results are negative, you will be randomly placed in one of two groups and receive either the standard drug, or you will be closely monitored without receiving the standard drug.

In this study, you will also be asked to complete a few questionnaires at different times, to understand your quality of life.

How can I find out more or join the study?

Talk to your cancer doctor if you are considering joining this study. You can share summaries like this with them and ask if they think joining the trial may be a good option for you.

Before you join this study, you will be asked to review an *Informed Consent* document which will tell you more about why the research is being done and your role as a participant. You will have an opportunity to discuss anything that is not clear and ask any questions you have.

Joining this study is entirely up to you and you can decide to leave at any time without giving a reason. Your decision to join or leave the trial will not affect your standard medical care.

The **BLC.6** study is currently enrolling patients at cancer centres in Canada. For a full list of participating cancer centres please visit www.clinicaltrials.gov and search using NCT05987241. (https://clinicaltrials.gov/study/NCT05987241)

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