A metastatic urothelial cancer clinical trial

Testing the addition of an anti-cancer drug to the usual immunotherapy treatment in patients with metastatic urothelial cancer

BLC.5 | NCT05092958

What is the purpose of this study?

The purpose of this study is to see if adding a new drug to other drugs which are commonly used to treat metastatic urothelial cancer is better than the commonly used drugs alone.

Why is this study important?

The new drug being studied is a new type of drug being developed for the treatment of metastatic urothelial cancer. There is some evidence that this new drug, in combination with immunotherapy agents is effective in shrinking or stabilizing your type of cancer, but more evidence is required to be able to consider adding this to current treatment.

Who can participate in this study?

This trial is for adults 18 years of age or older with metastatic urothelial cancer, who have received no more than one drug combination that included platinum chemotherapy within the last year.

This trial is for individuals who:

- Have cancers that did not grow/spread following prior treatment.
- Have completed prior chemotherapy between 3 and 10 weeks ago.
- Have not received prior immunotherapies

This trial is not for individuals who:

- Are pregnant or plan to become pregnant
- Are on immunosuppressive medications or anticoagulation drugs
- Have a history of heart, lung or gastrointestinal disorders
- Have had an organ or stem cell transplant
- Who have a malignant cancer diagnosed within the last 3 years, except for curable cancers that have been treated

CLINICAL TRIAL SPONSOR
Canadian Cancer Trials Group
Groupe canadien des essais sur le cancer

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 new drug may not be as good as the usual approach. 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: diarrhea, tiredness, loss of appetite, redness, pain or peeling of palms and soles, and high blood pressure. 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 randomly placed in one of two groups and you will receive either the drug commonly used to treat this disease, or the new drug in combination with the commonly used drug.

You will also be asked to complete a few questionnaire(s), and a diary at different times, to understand your Quality of Life, and record the number of pills you take.

How can I find out more or join the study?

Always talk to your doctors and other health care providers if you are considering joining a clinical trial. You can share summaries like this with them and ask if they think joining the trial may be a good option for you.

The BLC.5 **study** is currently enrolling patients at centres in Canada. For a full list of participating centres please visit www.clinicaltrials.gov and search using NCT05092958: (https://clinicaltrials.gov/ct2/show/NCT05092958)

Before you decide to join any clinical trial, you will be asked to review an *Informed Consent* document. Discussion with your physician and the informed consent document will tell you more about why the research is being done and your role as a participant. Please ask the study doctor if anything is not clear or if you if you have questions.

Joining clinical trials 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.