A skin cancer clinical trial



Testing the addition of an immunotherapy drug to the usual surgery for advanced skin cancer

SKC.1 | NCT06568172

What is the purpose of this trial?

The purpose of this study is to compare the effects of the usual approach alone to using the study drug plus the usual approach on you and your skin cancer.



The usual treatment for patients with advanced skin cancer is the removal of the cancerous tissue (surgery) with or without radiation.

Why is this trial important?

This study is important because we want to find out if this approach is better or worse than the usual approach for your type of skin cancer. There is evidence that this immunotherapy drug is effective in shrinking or stabilizing the cancer. This study may help the researcher learn things that may help other people in the future.

Who can participate in this study?

This trial is for:

- Individuals with advanced skin cancer, that can be removed with surgery and that has not been treated before
- Individuals 18 years of age or older



This trial is not for:

- Individuals pregnant or nursing
- Individuals whose cancer has spread to other parts of their body
- Individuals with a known history of major cardiac disease or transplant (organ or stem cell)
- Individuals with a current infection that requires antibiotics given through the vein, antivirals, or antifungal treatments
- Individuals with an autoimmune disease

What are the risks?



If you choose to take part in this study, there is a risk that the study approach may not be as good as the usual approach for your cancer at extending the amount of time without your cancer returning. There is also a risk that you could have side effects from the

study immunotherapy drug. These side effects may be worse and may be different than you would get with the usual approach for your cancer.

Some of the most common side effects that the study doctors know about with the immunotherapy drug used are:

- tiredness
- diarrhea
- nausea
- rash or itching
- hormone gland changes
- Reaction during or following infusion of the drug

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 usual approach to treat your skin cancer or you will receive the study drug plus the usual approach. 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 **SKC.1 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 NCT06568172.

