



CCTG IC8 clinical trial for cancer patient's at risk from COVID-19
A study of an immunization to prevent severe respiratory infections

A clinical trial for cancer patient's at risk from COVID-19

Immunization to prevent severe respiratory and COVID-19 related infections in cancer patients

If you are a cancer patient currently undergoing treatment, you may be able to consider joining this study.

What is the purpose of this trial?

The purpose of the trial is to find out if immunization with a new immune-stimulator will prevent or reduce severe respiratory and COVID-19 infections in cancer patients. A new type of immune stimulating therapy is being developed for the treatment of cancer. It works by activating the parts of your immune system involved with protecting against viral and bacterial infections. It has been studied in over 300 cancer patients who have also been receiving other cancer treatments and seems promising. But it is not yet clear if it can offer better results than not having the immunization at all.

Why is this trial important?

Cancer patients, while undergoing treatment, are at higher risk for COVID-19 because of a compromised immune system and the need for frequent visits to a cancer centre. There is currently no vaccination available for COVID-19. The new immune stimulator also shows promise in tolerability for individuals with compromised immune systems.

Who can participate?

- **This trial is for:** Adults receiving treatment at specific Canadian Cancer Centres, based on the highest risk of COVID infection.
- **This trial is not for:** Cancer patients not undergoing treatment, or previously tested positive for COVID-19

What can I expect?

You will be randomly assigned to one of two groups.



Group 1
Will receive three doses of the new immune stimulator at the start of the trial, on day 14, and day 45.



Group 2
Will not receive immunization but will have virtual follow-up at start of trial, day 14, and day 45.

Both groups will have follow-up 28 days later, then every 2 months for 1 year, and periodic blood tests to see how your immune system responds. This may include genetic testing to help explain why some people respond better. Permission to link to your health information is required to follow your health and the study treatment.

If the study results show that the new immune stimulator reduces severe respiratory and COVID-19 infections, it will be set aside for participants randomized to the observation arm.

What are the risks?

There are currently no risks or side effects associated with the new immune stimulator are considered very likely. The most common less likely (between 5 and 20% of people) side effects are injection site reaction and possible flu-like symptoms. Details of all side effects including rare (4% and less of people) can be found in the consent document that you will review before joining the trial.

How can I find out more?

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 CCTG IC8 study is currently open at centres in Canada. For a full list of participating centres please visit www.clinicaltrials.gov and search using NCT04442048.

This trial is sponsored by the Canadian Cancer Trials Group