A melanoma clinical trial

Comparing immunotherapy alone to immunotherapy combined with a new treatment for patients with advanced melanoma

ME.17 | NCT06623461

What is the purpose of this study?

The purpose of this study is to investigate the effects of adding a new treatment to the standard treatment (immune checkpoint blockade, or ICB) for advanced melanoma compared to the standard treatment given alone.

Why is this study important?

The new treatment being studied is being developed for the treatment of advanced melanoma, in combination with the standard treatment (ICB). The new treatment has been studied in some people and seems promising, but it is not clear if it can offer better results than standard treatment alone.

Who can participate in this study?

This trial is for:

- People 18 years of age or older with melanoma that has spread from where it first started (advanced disease)
- People with no prior ICB treatment for their advanced melanoma
- People that can swallow medications

This trial is not for:

- People who have been treated with antibiotics in the last 14 days
- People with regular corticosteroid use >10mg a day by mouth or injection
- People with active viral infections, Hepatitis B or Hepatitis C, or any uncontrolled autoimmune disease
- People that have received live vaccines in the last 30 days
- People that are pregnant or breastfeeding and/or expecting to conceive or father children

What are the risks?

If you choose to take part in this study, there is a risk that the new treatment added to the current standard treatment may not be as good as the standard treatment alone. There is also a risk that you could have side effects from the new treatment. Some of the most common side effects that the study doctors know about are diarrhea, nausea, flatulence, and change in stool appearance. 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 new treatment with standard treatment (ICB), or the standard treatment alone (ICB).

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 **ME.17** study is currently enrolling patients at cancer centres in Canada. For a full list of participating cancer centres please visit https://clinicaltrials.gov/study/NCT06623461