Melanoma Clinical Trial

Using a new drug alone or combined with standard treatment to prevent mucosal melanoma return after surgery

MEC.6 | NCT05111574

What is the purpose of this study?

The purpose of this study is to compare the effects on you and your mucosal melanoma of a new drug with the usual treatment compared to a placebo with the usual treatment.

Why is this study important?

The new drug being studied is a type of drug being developed for the treatment of melanoma. Laboratory tests show that it may help slow the growth of melanoma. The new drug has been studied in a few people and seems promising, but it is not clear if it can offer better results than standard treatment.

Who can participate in this study?

This trial is for adults 18 years of age or older with mucosal melanoma that has either been fully removed or that is not removable by surgery.

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 fatigue, rash, diarrhea, inflammation of the liver, high blood pressure, nausea, or vomiting. You will find details of all side effects in the consent document.

CLINICAL TRIAL SPONSOR
Canadian Cancer Trials Group
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SHARE THIS SUMMARY WITH YOUR **HEALTH CARE TEAM**
TO SEE IF THIS TRIAL IS A GOOD OPTION FOR YOU.

What can I expect?

This study has 2 separate groups. The part you join will depend on what your stage of cancer is.

If tests show your cancer has been fully removed by surgery, you will take part in Group 1. If in Group 1, you will randomly receive either the new drug or a placebo, along with the drug which is commonly used to treat this disease. You and your study doctor will not be told which arm you are in

If tests show your cancer has not been fully removed or has spread, you will take part in Group 2. If you are in Group 2 you will receive the new drug along with the drug which is commonly used to treat this disease.

In this study, you will also be asked to complete a pill diary and one short fatigue questionnaire after you are registered for the study, but before you start any treatment.

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 MEC.6 study is currently accruing at centres in Canada. For a full list of participating centres please visit www.clinicaltrials.gov and search using NCT05111574.

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.