A Breast Cancer Clinical Trial

Treatment with immunotherapy vs. observation in people with triple-negative breast cancer who had a good response after initial (neoadjuvant) treatment with chemotherapy and immunotherapy

MAC.29 | NCT05812807

What is the purpose of this study?

The purpose of this study is to determine if observation after surgery is as effective as completing 6 more months of immunotherapy in patients with early-stage triple-negative breast cancer (TNBC) who have completed standard treatment before surgery and who have had a good response.

Why is this study important?

The usual approach for early-stage triple-negative breast cancer patients is to continue to receive immunotherapy after surgery. If the study shows that observation after surgery is just as effective, future patients may be able to avoid the additional weeks of treatment and its associated side effects.

Who can participate in this study?

This trial is for people who meet the following conditions:

- 18 years of age or older
- Triple Negative Breast Cancer
- Surgery has removed all disease
- Able to enter the study within 3 months after final surgery

This trial is not for people with the following conditions:

- Pregnant or nursing
- Intolerance or hypersensitivity to immunotherapy treatments
- Medical conditions that require treatment with steroids or treatments that weaken the immune system
- Active liver 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 reducing the risk of your cancer coming back. There is also a risk that you could have side effects from the immunotherapy treatment. Some of the most common side effects that the study doctors know about are tiredness, nausea, loss of appetite, back pain, joint stiffness, and cough. 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 27 weeks of immunotherapy treatment, or you will not receive any further treatment and will have regular appointments with the study doctors who will monitor your health. All study participants will have regular follow-up appointments with the study doctors for 10 years after entering the study.

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 MAC.29 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 NCT05812807. A direct link to the study website is here: https://www.clinicaltrials.gov/study/NCT05812807?term=NCT05812807&rank=1

{for participating Centre's use - contact information, enrollment instructions, logo}