A breast cancer clinical trial

A new drug and a commonly used drug compared with a commonly used drug alone in preventing relapses in people with high risk HER2-positive breast cancer.

MAC.27 | NCT04457596

What is the purpose of this study?

The purpose of this study is to find out if the combination of a new drug and a commonly used drug is better than the commonly used drug alone at preventing this type of breast cancer from returning.

Why is this study important?

The new drug is approved for HER2+ advanced or metastatic breast cancer but it is unclear how well it would work for early-stage high risk patients when combined with the standard treatment. This trial is to determine if the combination of the new drug and the standard treatment is better than standard treatment alone.

Who can participate in this study?

This trial is for adults 18 years of age or older with breast cancer who have human epidermal growth factor receptor 2 (HER2)-positive breast cancer.

This study is for:

- Patients with HER2-positive breast cancer.
- Patients who have not received treatment with a new anti-cancer drug within 28 days prior to starting this study.
- Those who have had cancer surgically removed from the breast and lymph nodes.

This study is not for:

- Patients with stage IV (cancer cells have spread from one part of the body to another) breast cancer.
- Patients with a history of invasive breast cancer within the last 3 years.
- Patients with cancer that returned after treatment and surgery.
- Patients with known active and/or untreated Hepatitis B or Hepatitis C or chronic liver disease.
- Patients who had major surgery not related to breast cancer or a significant injury within 28 days prior to starting the study.
- Those who are pregnant and/or breastfeeding.

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

What are the risks?

If you choose to take part in this study, there is a risk that the new drug combination may not be as good as the usual approach. There is also a risk of side effects from the new drug. Some of the most common side effects that the study doctors know about are: nausea, diarrhea, tiredness, vomiting, and decrease in the number of red blood cells (anemia). 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. One group will receive the new drug and another drug which is commonly used to treat this cancer. The second group will receive a placebo (a pill that looks like the study drug but contains no medication) and the other drug that is commonly used to treat this cancer. In this study, you will also be asked to complete a diary at different times to record the number of pills you take.

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 **MAC.27 study** is currently enrolling patients at centres in Canada. For a full list of participating centres please visit www.clinicaltrials.gov and search using **NCT04457596**.

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 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.