A breast cancer clinical study

Testing the addition of a new drug to the usual radiotherapy in preventing relapse in people with inflammatory breast cancer

MAC.26 | NCT03598257

What is the purpose of this study?

The purpose of this study is to find out if a new drug helps prevent your inflammatory breast cancer from returning when given with radiotherapy.

Why is this study important?

The new drug has been found to block some of the enzymes needed for cell growth, but it is unclear how well it does this in inflammatory breast cancer. Blocking these enzymes may make the inflammatory breast cancer more sensitive to radiotherapy, which is a common treatment for this cancer. 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 study is for adults aged 18 years or older with inflammatory breast cancer whose disease has not spread to other parts of the body.

This study is for:

- Patients who have had their breast cancer surgically removed 3-12 weeks before starting this study.
- Patients who received chemotherapy before their breast cancer was surgically removed.
- Patients who are able to swallow oral medications.

This study is <u>not</u> for:

- Patients who have previously received radiotherapy to the chest or lymph nodes.
- Patients who plan to take other study drugs during radiotherapy.
- Patients with heart conditions.
- Patients who are pregnant or breastfeeding.
- Patients who have had major surgery within 2 weeks of starting the study or are recovering from major surgery.

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 are the risks?

If you choose to take part in this study, there is a risk that treatment with the new drug might not be as good as the standard treatment. 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, abdominal pain, diarrhea, tiredness, 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. In Group 1, you will receive the new drug and radiotherapy. In Group 2, you will receive only radiotherapy which is commonly used to treat this disease. The new drug would be provided as a tablet and would need to be taken daily while radiotherapy is being given. If you are taking the study drug, you will also be asked to complete a diary to record the number of pills you take.

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.26 study** is currently enrolling patients at centres in Canada. For a full list of participating centres please visit www.clinicaltrials.gov and search using **NCT03598257** or use this direct link https://clinicaltrials.gov/search?term=NCT03598257

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