A Breast Cancer Clinical Trial

Testing the usual treatment of radiation therapy and hormonal therapy to hormonal therapy alone for low-risk, early-stage breast cancer

MAC.28 | NCT04852887

What is the purpose of this study?

The purpose of this study is to compare the usual treatment of breast radiation and hormonal drugs after lumpectomy to using hormonal drugs alone for 50 to 70 year old people with low risk breast cancer. The removal of breast radiation from the usual treatment may have no effect on whether your cancer returns, and it could also reduce side effects.

Why is this study important?

This study is being done to answer the following question: Is treatment with hormonal therapy as good as the usual treatment of radiation and hormonal therapy in people with low-risk breast cancer who have had a lumpectomy?

Researchers want to find out if this approach is better or worse than the usual approach for low-risk breast cancer. The usual approach is defined as care most people get for low-risk, early-stage breast cancer that is sensitive to hormones.

Who can participate in this study?

This trial is for adults between the ages of 50 and 70 years old who have low-risk, early-stage breast cancer that is sensitive to hormones.

This trial is for:

- Patients with an Oncotype DX Recurrence Score equal to or less than 18 (a type of genetic test).
- Patients with HER2-negative, ER- and/or PgR-positive breast cancer.
- Those who have had the cancer surgically removed from their breast (lumpectomy).
- Patients who plan to take hormonal drugs for a minimum of 5 years.

This trial is not for:

- Patients whose cancer has spread from one body part to another.
- Those who had a mastectomy.
- Patients that have received radiation therapy, chemotherapy, biotherapy, and/or hormonal therapy prior to joining the study.
- Those who are pregnant and/or breastfeeding.

What are the risks?

If you choose to take part in this study, getting less treatment after lumpectomy may not be as good as the usual approach at preventing your cancer from coming back. Researchers will monitor this closely. You will find details of all the risks 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 usual treatment of breast radiation therapy and hormonal therapy. In Group 2, you will receive only hormonal therapy.

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.28 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 NCT04852887.