A breast cancer clinical trial

Comparing two commonly used treatment choices for early-stage breast cancer in premenopausal women

CCTG MAC.30 | NCT05879926

What is the purpose of this study?

The purpose of this study is to compare two commonly used treatment choices for early-stage breast cancer in premenopausal women. **Testing the addition of chemotherapy to the usual treatment of ovarian function suppression plus hormonal therapy in premenopausal ER-positive/HER2-negative breast cancer patients who are at high risk of cancer returning.**

Why is this study important?

Patients with this type of early-stage breast cancer may receive chemotherapy as part of their usual care. It is not clear with current information how much more benefit chemotherapy adds and if putting women into early menopause may give the same benefit as chemotherapy. The addition of chemotherapy to the other usual treatment could prevent your cancer from returning. But, it could also cause more side effects.

Who can participate in this study?

This trial is for:

- Female patients 18 years of age or older
- Patients must be premenopausal
- Patient may have undergone a total mastectomy, skin-sparing mastectomy, nipple-sparing mastectomy, or a lumpectomy
- The tumour must be ER and/or PgR-positive and HER2-negative

This trial is not for:

- Patients with metastatic disease
- Patient with history or symptoms of cardiac disease
- Patients who have already received treatment for this breast cancer with radiation, chemotherapy or biotherapy

What are the risks?

If you choose to take part in this study, there is a risk that using chemotherapy may not be as good as the other usual approach for preventing your cancer from coming back.

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 treatment with ovarian suppression and hormonal therapy, or treatment with ovarian suppression and hormonal therapy plus chemotherapy.

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.30** study is currently enrolling patients at cancer centres in Canada. For a full list of participating cancer centres please visit https://www.clinicaltrials.gov/study/NCT05879926?term=NCT05879926&rank=1