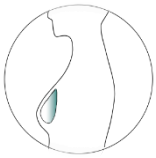
A breast clinical trial



An advanced breast cancer screening clinical trial for patients who have progressed on current treatment

IND.241 | NCT05601440

What is the purpose of this trial?

This trial/study consists of a number of independent studies or "substudies", each of which is testing a different drug or combination of drugs.

The purpose of the study is to see if DNA abnormalities in your cancer or "biomarkers" can help predict how certain cancers may respond to certain treatments.

The first part of this trial uses biomarker testing to identify which substudy, and therefore which treatment, patients will be assigned to.

Why is this trial important?

This study will help researchers to better understand if certain biomarkers may help to identify which patients may do better on certain treatments.

Who can participate in this study?

This trial is for people:

- with ER positive, HER2 negative, advanced breast cancer
- who received at least 24 weeks of a CDK inhibitor plus endocrine therapy
- who progressed on a CDK inhibitor plus endocrine therapy during treatment or within 8 weeks after finishing treatment
- who can swallow drugs taken by mouth and do not have any gastrointestinal problems that may affect absorption

This trial is <u>not</u> for people:

- who are being currently treated for another cancer
- with active or uncontrolled infections or serious illnesses/medical conditions
- with significant heart conditions
- who are pregnant or breastfeeding

You will find complete details of who this trial is for by visiting https://clinicaltrials.gov/study/NCT05601440

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 screening study and are eligible for a treatment substudy, there is a risk that the study treatment you receive will not work for your cancer.

Biomarker screening may identify biomarkers for specific substudies, but these substudies may not be open for your to participate in, or you may not be eligible.

You will find details of all risks of biomarker testing in the consent document and if eligible for a treatment substudy, more information on the substudy and the details of all side effects of the drugs to be used in the substudy consent document.

What can I expect?

If you choose to take part in this study, you will be entered into the trial and first have a blood test to see if you have specific biomarkers that will be used to assign you to a treatment substudy. You will receive more information on the treatment substudy options once your biomarker testing is completed; this usually takes 2-3 weeks.

The treatment substudy options will depend on your biomarker results, eligibility requirements for each substudy and which substudies are available when you are ready to start treatment. If no biomarker changes are found that would assign you to a specific substudy, you will be randomly assigned to a substudy.

If a substudy is available for you and you choose to take part, you will be enrolled to that substudy and will receive a new drug or combination of drugs.

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 **IND.241 study** is currently enrolling patients at cancer centres in Canada. For a full list of participating cancer centres please visit https://clinicaltrials.gov/study/NCT05601440.

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