ForPatients
by Roche

Breast Cancer Er-Positive Locally Advanced or Metastatic Breast Cancer Breast Cancer Estrogen Receptor (ER)-Positive Breast Cancer HER-2 Negative

A clinical trial to compare GDC-9545 with a doctor's choice of hormonal therapy in people with advanced or metastatic breast cancer after previous treatment has not worked.

A Study Evaluating the Efficacy and Safety of GDC-9545 Compared With Physician's Choice of Endocrine Monotherapy in Participants With Previously Treated Estrogen Receptor-Positive, HER2-Negative Locally Advanced or Metastatic Breast Cancer

Trial Status	Trial Runs In	Trial Identifier
Active, not recruiting	17 Countries	NCT04576455 2020-001984-10 WO42312

The source of the below information is the publicly available website ClinicalTrials.gov. It has been summarised and edited into simpler language.

Trial Summary:

This Phase II, randomized, open-label, multicenter study will evaluate the efficacy and safety of giredestrant compared with physician's choice of endocrine monotherapy in participants with estrogen receptor (ER)-positive, human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer who have received one or two prior lines of systemic therapy in the locally advanced or metastatic setting.

Hoffmann-La Roche
Sponsor

Phase 2
Phase

NCT04576455 2020-001984-10 WO42312
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	>=18 Years	No

How does the WO42312 clinical trial work? This clinical trial is recruiting people who have a particular type of breast cancer. In order to take part, patients must have breast cancer that is advanced or metastatic (spread to other parts of the body) and has tested positive for estrogen receptors (ER-positive) and negative for HER2 (HER2-negative).

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The purpose of this clinical trial is to compare the effects, good or bad, of GDC-9545 with a doctor's choice of hormonal therapy in patients with this type of breast cancer. If you take part in this clinical trial, you will receive either GDC-9545 or your doctor's choice of hormonal therapy.

How do I take part in this clinical trial?
To be able to take part in this clinical trial, you must have been diagnosed with ER-positive, HER2-negative locally advanced or metastatic breast cancer. You must have received up to two previous treatments for breast cancer, one of which included hormonal therapy, taken for at least 6 months before the cancer got worse.

Your cancer must not have spread to the central nervous system or spinal cord, and you must not have any other significant health conditions.

If you think this clinical trial may be suitable for you and would like to take part, please talk to your doctor. If your doctor thinks that you might be able to take part in this clinical trial, he/she may refer you to the closest clinical trial doctor. They will give you all the information you need to make your decision about taking part in the clinical trial. You can also find the clinical trial locations on this page.

You will have some further tests to make sure you will be able to take the treatments given in this clinical trial. Some of these tests or procedures may be part of your regular medical care. They may be done even if you do not take part in the clinical trial. If you have had some of the tests recently, they may not need to be done again.

Before starting the clinical trial, you will be told about any risks and benefits of taking part in the trial. You will also be told what other treatments are available so that you may decide if you still want to take part.

While taking part in the clinical trial, premenopausal women who could become pregnant will need to either not have heterosexual intercourse or take contraceptive medication to avoid becoming pregnant for safety reasons.

Men whose partners who could become pregnant are also requested to use contraception to avoid pregnancy in their partner for safety reasons.

What treatment will I be given if I join this clinical trial?
Everyone who joins this clinical trial will be split into two groups randomly (like flipping a coin) and given either:

- GDC-9545, taken as a pill once-daily
- OR a hormonal therapy, taken as prescribed by your doctor

You will have an equal chance of being placed in the two groups.

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Men, and women who are not postmenopausal, will also need to take medication known as LHRH-agonist, starting 28 days before the trial starts and then every 28 days throughout the duration of the trial.

How long will I be seen in follow-up appointments and for how long?
You will be given the clinical trial treatment for as long as it can help you. During the trial, you will have appointments every 2 months for the first 18 months, and then every 3 months after that. These hospital visits will also include checks to see how you are responding to the treatment and any side effects that you may be having. You are free to stop this treatment at any time. After you finish treatment, you will have another visit one month after your last dose. The clinical trial doctors will also follow up with you at 3 months and then every 6 months after that, as long as you agree to it.

What happens if I am unable to take part in this clinical trial?
If this clinical trial is not suitable for you, you will not be able to take part. Your doctor may suggest other clinical trials that you may be able to take part in or other treatments that you could be given. You will not lose access to any of your regular care.

For more information about this clinical trial see the For Expert tab on the specific ForPatient page or follow this link to ClinicalTrials.gov: https://clinicaltrials.gov/ct2/show/NCT04576455?term=WO42312&draw=2&rank=1

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