ForPatients
by Roche

Breast Cancer

A study interested in understanding the mechanisms of resistance to antibreast cancer therapies

A Study to Investigate Mechanisms of Resistance to Breast Cancer Therapies

Trial Status	Trial Runs In	Trial Identifier
Recruiting	8 Countries	NCT06274515 WO44977

The information is taken directly from public registry websites such as ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com, etc., and has not been edited.

Official Title:

A Multi Cohort Translational Research Study to Investigate Mechanisms of Resistance to Breast Cancer Therapies

Trial Summary:

This study will evaluate mechanisms of resistance to anti-breast cancer therapies in tumor and blood samples from participants with human epidermal growth factor receptor (HER2) positive, hormone receptor (HR) positive or triple negative breast cancer.

Hoffmann-La Roche	Phase 4
Sponsor	Phase

NCT06274515 WO44977
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years	No

1. Why is the REMERGE clinical trial needed?

REMERGE is a scientific research study that does not use any treatment or new drug. The purpose of this study is to assess and understand the changes that happen to breast cancer over time, with the intention to improve breast cancer therapies or develop new therapies in the future. The data from this trial will help to better understand the biology of

breast cancer, which may explain the reasons for the uncontrolled growth of the cancer cells and why these are not responding well to some treatments.

2. How does the REMERGE clinical trial work?

The REMERGE study is designed for participants diagnosed with breast cancer who are being treated with an anti-cancer therapy.

Breast cancer patients will be asked to provide consent to donate tumor tissue and blood samples for testing if their disease starts to worsen. This study requires the participant to attend the clinic for one visit in person to collect samples of their tumor tissue and a small volume of blood. Total time of participation in the clinical trial will be about 3-4 weeks including time for follow up.

3. What are the main endpoints of the REMERGE clinical trial?

The main clinical trial endpoint (the main results measured in the trial) is to find out how tumors change during treatment for breast cancer in order to understand why anti-cancer therapies stop working.

The other clinical trial endpoints include to find out why some tumors do not respond to anti-cancer therapies, to compare findings in tumor tissue and blood, to better understand the disease and to support development of tests or tools that help with detecting or understanding the disease.

4. Who can take part in this clinical trial?

Participants can take part in this trial if they have breast cancer, if they received anti-cancer therapy and the disease starts to worsen, and if they provide consent to donate their tissue and blood samples.

Participants may not be able to take part in this trial if there are any risks of complications associated with the procedures to obtain the samples, if they discontinued the anti-cancer therapy for other reasons than their disease worsening or if they already started a new anti-cancer therapy.

5. What treatment will participants be given in this clinical trial?

Participants will not receive treatment within this clinical trial but will receive the therapies as per local regulations and guidelines.

6. Are there any risks or benefits in taking part in this clinical trial?

People who would like to participate will be told about any risks and benefits of taking part in the clinical trial, as well as any additional procedures, tests, or assessments they will be asked to undergo. All of these will be described in an informed consent document (a document that provides people with the information they need to decide to volunteer for the clinical trial).

Participants may have side effects (an unwanted effect of a procedure) from the procedures for collecting the samples obtained in this clinical trial. Participants will be monitored after the procedures during the clinical trial for safety assessments.

Potential benefits associated with the clinical trial

There are no direct benefits from donating the samples. However, research performed on these samples may help other people with similar medical conditions in the future.

Inclusion Criteria:

General Inclusion Criteria:

- Willingness to undergo a procedure to obtain tumor tissue (e.g. biopsy) and blood draw
- Diagnosis of HER2+, HR+ (for cohort R1) or triple negative breast cancer (for cohort T1) as per local assessment
- Availability of an archival tumor tissue (most recent pre-treatment tumor tissue is preferred)
- Unequivocally growing tumor lesion (progressive lesion) that is accessible for resection, excision or core needle biopsy
- Discontinuation of prior anti-cancer treatment outlined below should not be longer than 4 weeks from participation in this study

Inclusion criteria for participants in the cohorts studying acquired resistance

- Participant had undergone regular monitoring for disease progression as per local practice (preferably every 3-6 months) while on most recent breast cancer therapy
- Accessible tumor lesion that newly appeared or a lesion that started to regrow while the participant was at least 6 months on therapy

Inclusion criteria for participants in the cohort studying primary resistance

- Accessible tumor lesion that continued to increase in size or a newly appearing lesion (as confirmed by routine tumor assessment) while treated for at least 4 weeks but less than 6 months on therapy

Exclusion Criteria:

- Any risks factors that increase the risk of complications associated with the procedure to obtain tumor tissue (e.g. bleeding disorders)
- Any serious medical condition or abnormality in clinical laboratory tests that precludes an individual's safe participation in and completion of the study
- Participant has started treatment with subsequent anti-cancer therapy
- Participants whose progressive tumor lesion that is targeted for biopsy/resection is in the bone

- Discontinuation of treatment was due to a reason other than disease progression