ForPatients
by Roche

Breast Cancer Triple Negative Breast Cancer

An observational study to evaluate the prevalence of a cancer immunotherapy target and its role in patients with triple-negative breast cancer treated with systemic therapy (VANESSA)

A multi-country observational retrospective study to evaluate the prevalence of PD-L1 and its role in patients with triple-negative breast cancer treated with systemic therapy (VANESSA)

Trial Status	Trial Runs In	Trial Identifier
Recruiting	21 Countries	MO42921

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 observational study is also called a secondary data use non-interventional study or medical chart review study, which means that the study looks at medical data and tissue samples that have already been collected as part of routine medical practice.

The purpose of this study is to evaluate the role of a protein called programmed death-ligand 1 (PD-L1) in patients with triple-negative breast cancer (TNBC). Triple-negative breast cancer is a kind of breast cancer that does not have any of the receptors that are commonly found in breast cancer. The PD-L1 protein is found in tissue samples from patients with TNBC. Cells that produce a lot of PD-L1 protein, which are called PD-L1 positive, can partially resist or help the tumor evade the body's natural immune response. Blocking the PD-L1 protein may help the immune system to stop or reverse the growth of tumors.

The presence of PD-L1 protein in tumor tissue samples can be assessed with a laboratory test called the VENTANA anti-PD-L1 (SP142) assay.

This study will investigate how many patients with TNBC have tumors that are positive for the PD-L1 protein, and how being positive for PD-L1 affects the behavior of the tumor. The study will also assess whether the PD-L1 test results are consistent when measured in different laboratories.

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Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
Both	**>=18 years**	**No**

Who can participate?
Patients aged over 18 years with a diagnosis of eTNBC (early or locoregionally advanced TNBC, amenable to treatment with curative intent) or mTNBC (metastatic or locoregionally advanced unresectable TNBC, not amenable to treatment with curative intent) between 1st January 2014 and 31st December 2017, with a documented PD-L1 result.

What does the study involve?
Laboratory tests will be conducted on tissue samples that have already been taken from participants as part of medical routine care. Participants will not undergo any other surgical procedure for this study, and no additional tissue samples will be taken. Only tissue samples that have already been taken from a previous biopsy or surgical procedure can be used and collected by the study doctor.

A piece of body tissue sample will be tested by the local pathology laboratory to measure how much PD-L1 protein is present. The participant’s doctor will also send a small section of the participant’s tissue sample(s) to a study-designated central laboratory where the testing for PD-L1 will be performed.

The Ventana anti-PD-L1 (SP142) laboratory test will be used in both laboratories to measure the expression of the PD-L1 protein. The results of these tests are not intended to be used (as part of this study) to recommend treatment options.

If the patient signs the optional additional consent, testing may involve analysis of the participant’s genome (DNA), the "instruction book" for the cells in the body. Participant’s samples may be tested for inherited or non-inherited genome variations, to allow for exploration of broad health research questions across disease areas. Testing may include analysis of all of body DNA (whole genome sequencing) or analysis of part of participant’s DNA. Analyses of samples from a large number of people may help researchers learn more about breast cancer and other diseases, possible links among diseases, mutations and how they might affect a disease or a person's response to treatment, and new avenues for drug development and personalized therapies

What are the possible benefits and risks of participating?
There is no direct medical benefit to participants from being in this study. The information gained from this study may help researchers and doctors to learn more about how to treat

patients with TNBC. Participants and other patients with TNBC or a similar condition may benefit from the results of such research in the future.

The Research Biosample Repository (RBR) tissue sample will be taken from a sample that was collected before this study, so there are no additional risks. Although care is taken to not exhaust the archival tissue blocks, there remains a small risk that the tissue might get used up. There are no additional risks associated with donating participants' leftover samples to the RBR.

Where is the study run from?
F. Hoffmann-La Roche (Switzerland)

When is the study starting and how long is it expected to run for?
June 2021 to September 2022

Who is funding the study?
F. Hoffmann-La Roche (Switzerland)

Who is the main contact?
Trial Information Support Line
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