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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)

Submission date
18/09/2021

Recruitment status
No longer recruiting

Registration date
12/01/2022

Overall study status
Completed

Last Edited
01/02/2022

Condition category
Cancer

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
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.

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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Contact information

Type(s)
Public

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
303428

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
MO42921, IRAS 303428, CPMS 50835

Study information

Scientific Title
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)

Study objectives
To evaluate the prevalence of PD-L1 positivity on primary or metastatic tissue among early TNBC (eTNBC) and metastatic TNBC (mTNBC) patients treated with systemic therapy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 06/09/2021, Ethics Committee for Clinical Research at Pauls Stradins Clinical University Hospital Development Society (Pilsonu Street 13, Riga, LV- 1002, Latvia; +371 (0) 26380055; etikas-komiteja@stradini.lv), ref: 260821-1E (for English version) and 260521-1L (for Latvian version)

Study design
Observational multi-country study with secondary data use (NIS SDU) from two cohorts

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet

Health condition(s) or problem(s) studied
Triple-negative breast cancer treated with systemic therapy

Interventions
Approximately 2,700 patients with a new diagnosis of eTNBC or mTNBC between 1st January 2014 and 31st December 2017 will be considered for inclusion in this study. Medical/treatment history data will be retrospectively extracted from medical records and archived tissue samples will be analyzed. Archived tumor tissue samples from the primary and/or metastatic lesion will be tested for PD-L1 using the Ventana PD-L1 (SP142) assay.

Intervention Type
Other

Primary outcome measure
PD-L1 positivity, as defined by expression on tumor-infiltrating immune cells covering ≥1% of tumor area by IHC using the Ventana PD-L1 (SP142) assay, measured at a single timepoint

Secondary outcome measures
Inter-observer concordance on PD-L1 positivity using the Ventana PD-L1 (SP142) assay between local and central laboratories, measured at a single timepoint

Overall study start date
03/06/2021

Completion date
30/09/2022

Eligibility

Key inclusion criteria
1. Signed Informed Consent Form, if and as required, according to local laws and regulations
2. Aged ≥18 years at the time of diagnosis
3. Histologically documented TNBC, assessed locally and defined as ER and PR positivity of less than 1% and HER2 IHC0, IHC1+, or IHC2+/ISH-, as determined according to ASCO/CAP guidelines
4. New 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
5. Available formalin-fixed paraffin-embedded (FFPE) tumor tissue of good quality based on total and viable tumor content for local and central laboratory PD-L1 testing
6. Documentation of tissue source (primary breast cancer, de novo breast cancer, metastatic tumor location), biopsy or resection, tissue size and tumor content
7. Patients who received any systemic therapy in early-stage disease and/or in metastatic setting

8. Only patients with documented, locally determined PD-L1 status using Ventana PD-L1 (SP142) assay by trained pathologists, will be eligible for central testing and their data will be included in the study analysis

Participant type(s)
Patient

Age group
Mixed

Sex
Both

Target number of participants
2700

Key exclusion criteria
1. No available archival tumor tissue for PD-L1 testing
2. Tissue samples of poor quality based on total and viable tumor content and/or bad fixation
3. Fine needle aspiration, brushing, cell pellet from pleural effusion, bone metastases, and lavage samples are not acceptable
4. Patients whose tumor tissue is not evaluable for local and central testing

Date of first enrolment
30/09/2021

Date of final enrolment
30/09/2022

Locations

Countries of recruitment
Algeria

Chile

England

Finland

Germany

India

Italy

Kenya

Korea, South

Latvia

Lebanon

Lithuania

Morocco

Peru

Russian Federation

Saudi Arabia

Serbia

South Africa

Tunisia

Türkiye

United Kingdom

Viet Nam

Study participating centre
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Santiago
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Study participating centre
Centre anti Cancer Annaba
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Algeria
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Study participating centre
Pierre and Marie Curie Cancer Center
Place du 1er Mai
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Study participating centre
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Study participating centre
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Study participating centre
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Study participating centre
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Study participating centre
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Study participating centre
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Study participating centre
American University of Beirut Medical Center
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Beirut
Lebanon
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Study participating centre
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Sponsor information

Organisation
Roche (Switzerland)

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Sponsor type
Industry

Website
https://www.roche.com/about_roche/roche_worldwide.htm

ROR
https://ror.org/00by1q217

Funder(s)

Funder type
Industry

Funder Name
F. Hoffmann-La Roche

Alternative Name(s)
Hoffman-La Roche, F. Hoffmann-La Roche Ltd.

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
Switzerland

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
31/12/2023

Individual participant data (IPD) sharing plan
The participant dataset is not available; this is not required by regulation.

IPD sharing plan summary
Not expected to be made available