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Using advanced technologies to better understand breast cancer and its environment

Submission date
23/04/2026

Recruitment status
Recruiting

Registration date
29/05/2026

Overall study status
Ongoing

Last Edited
20/05/2026

Condition category
Cancer

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

Plain English summary of protocol

Background and study aims
This study is a non-interventional research project in people with early-stage breast cancer who are receiving standard neoadjuvant treatment before surgery. The study does not change the treatment chosen for patients. Instead, it collects tumour tissue and blood samples during routine care to better understand why some breast cancers respond well to treatment while others do not. The study includes different breast cancer subtypes, including triple-negative, HER2-positive, and high-risk hormone receptor-positive/HER2-negative disease.

Breast cancers are not all the same. Even within one tumour, different groups of cancer cells and surrounding non-cancer cells may behave differently. Researchers believe that this tumour heterogeneity, together with the immune and stromal cells around the tumour, may influence response to chemotherapy, immunotherapy, risk of relapse, and long-term outcome.

This study aims to build a more detailed picture of how breast cancer cells, immune cells, and other cells in the tumour environment interact and change under treatment pressure. The researchers also want to identify biological features linked to pathological complete response, disease-free survival, and treatment resistance, and to explore whether these findings could help develop better biomarkers and more personalized treatment strategies in the future.

Who can participate?
Adult patients aged 18 years and over with histologically confirmed early-stage breast cancer planned for neoadjuvant systemic treatment at Institut Jules Bordet.

What does the study involve?
Researchers will collect samples before treatment and at surgery, with an optional additional biopsy during treatment. Blood samples will also be collected at several timepoints during treatment and follow-up. These samples will be used for a range of laboratory analyses, including bulk DNA and RNA sequencing, DNA methylation analysis, single-cell sequencing, spatial transcriptomics, circulating tumour DNA analysis, multiplex imaging, and immune profiling. In some cases, fresh tumour tissue will also be used to develop patient-derived organoids, which are miniature laboratory models grown from a patient’s tumour.

What are the possible benefits and risks of participating?
This study is unlikely to provide a direct benefit to participants, because it does not change treatment. However, it may improve understanding of breast cancer biology, treatment response, and resistance, and may help future patients through the development of improved biomarkers and personalized treatment approaches. Risks are mainly related to additional blood draws and any optional research biopsy, including pain, bruising, bleeding, discomfort, dizziness, and, rarely, infection or biopsy-related complications. No additional treatment-related risk is expected, as participation does not modify standard clinical care.

Where is the study run from?
The Institut Jules Bordet, Belgium.

When is the study starting and how long is it expected to run for?
April 2020 to December 2030.

Who is funding the study?
Breast Cancer Research Foundation, USA.

Who is the main contact?
Prof Christos Sotiriou, christos.sotiriou@hubruxelles.be

Contact information

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Principal investigator, Scientific, Public

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Study information

Scientific Title
Molecular characterization of intratumor heterogeneity of different breast cancer subtypes and their microenvironment using multiomic platforms and patient-derived models: a prospective pilot study

Acronym
MultiOmics

Study objectives
Primary objective:
To prospectively study molecular intratumor heterogeneity and the tumor microenvironment in different breast cancer subtypes during neoadjuvant treatment using integrated multiomic analyses and patient-derived models.

Secondary objectives:
To evaluate tumor, stromal, and immune features using bulk, single-cell, spatial, epigenetic, and circulating tumor DNA analyses; to study immune repertoire diversity and systemic immune responses; to explore associations with pathological complete response and disease outcome; and to assess the feasibility of generating patient-derived breast cancer models.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 22/10/2019, The Ethics Committee of the Institut Jules Bordet – ECPSO/LEC Accreditation number OM011 (HUB - Institut Jules Bordet / Jules Bordet Instituut Rue Meylemeersch / Mijlenmeersstraat, 90, Brussels, 1070, Belgium; + 32 (0)2541 35 95; Comite. ethique. bordet@ hubruxelles.be), ref: CE2989/01.09.2025; BECT: B079201939700

Primary study design
Observational

Secondary study design
Cohort study

Study type(s)

Health condition(s) or problem(s) studied
Early-stage ER-positive, HER2-negative luminal high-risk breast cancer, HER2-positive breast cancer, triple-negative breast cancer treated with standard of care neoadjuvant therapies.

Interventions
This is a prospective, single-centre, observational translational pilot study in patients with early-stage breast cancer receiving standard-of-care neoadjuvant treatment.
Eligible patients with triple-negative, HER2-positive, or ER-positive/HER2-negative high-risk luminal breast cancer are enrolled at Institut Jules Bordet.

The study does not alter treatment decisions.
Tumour tissue and blood samples are collected prospectively before treatment, at surgery, and optionally during treatment; additional longitudinal blood samples are collected during follow-up.
Collected samples include FFPE tissue, frozen tumour tissue, fresh tumour tissue, plasma, serum, peripheral blood mononuclear cells, and one germline reference blood sample.
Multiomic analyses include bulk DNA and RNA sequencing, DNA methylation profiling, single-cell sequencing, spatial transcriptomics, multiplex imaging, and circulating tumour DNA analyses.
Fresh tumour samples may also be used to generate patient-derived models.
Molecular, cellular, spatial, and immune profiling data are integrated with clinicopathological and outcome data to study intratumour heterogeneity, tumour microenvironment composition, systemic immune response, treatment response, and disease outcome.

Intervention Type
Other

Primary outcome(s)
1. Feasibility of integrated multiomic characterization of intratumor heterogeneity and the breast cancer microenvironment measured using the percentage of enrolled patients with successful collection of analyzable pre-treatment and post-treatment tumour and blood samples for planned multiomic translational analyses at baseline and surgery, with optional on-treatment sampling before week 4; additional protocol-defined longitudinal blood sampling during treatment and follow-up, with outcome follow-up up to 5 years post-enrolment

Key secondary outcome(s)

Completion date
29/12/2030

Eligibility

Key inclusion criteria
1. Adult patients aged 18 years or older
2. Histologically confirmed early-stage breast cancer planned for neoadjuvant systemic treatment at Institut Jules Bordet
3. Breast cancer subtype eligible for this observational translational study:
3.1. Triple-negative breast cancer, or
3.2. HER2-positive breast cancer,
3.3. ER-positive/HER2-negative high-risk luminal breast cancer
4. No evidence of metastatic disease at study entry
5. Willing and able to provide written informed consent for collection of tissue, blood, and clinical data
6. Availability of baseline and planned surgical material, with optional on-treatment biopsy where feasible
7. For the TNBC expansion cohort: tumor size at least T1c with node-positive disease, or tumor size at least T2, or otherwise eligible for neoadjuvant pembrolizumab plus chemotherapy according to KEYNOTE-522 and institutional multidisciplinary tumor board decision

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
90 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Patients not meeting the inclusion criteria
2. Metastatic breast cancer at study entry
3. Refusal or inability to provide informed consent
4. Inability to provide the required research samples according to protocol procedures

Date of first enrolment
20/04/2020

Date of final enrolment
31/12/2027

Locations

Countries of recruitment
Belgium

Sponsor information

Organisation
Institut Jules Bordet

ROR
https://ror.org/05e8s8534

Funder(s)

Funder type

Funder Name

Breast Cancer Research Foundation

Alternative Name(s)
BREAST CANCER RESEARCH FOUNDATION INC, The Breast Cancer Research Foundation, The Breast Cancer Research Foundation, Inc., Breast Cancer Research Foundation, Inc., BCRF

Funding Body Type
Government organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available