Real-world data of treatment patterns, outcomes and genomic profiling in early breast cancer in Greece (SONATA study)

First published: 04/01/2025

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Study Ongoing

Administrative details

EU PAS number

EUPAS1000000428

Study ID

1000000428

DARWIN EU® study

No

Study countries

☐ Greece

Study description

SONATA is a research collaboration between the Oncology Department at Iatriko Diavalkaniko Thessalonikis Hospital in Greece and Novartis, focusing on early breast cancer (eBC) patients.

Research Collaboration Details: The collaboration is represented by Iatriko Athinon (Iatriko Diavalkaniko Thessalonikis Hospital) and Dr. Konstantinos Papazisis (Primary Investigator) and involves Novartis Hellas contributing scientifically to the research.

Study Overview: The study, titled "Real-world data of treatment patterns, Outcomes and genomic profiling in early breast cancer in Greece" (SONATA study), aims to describe patient demographics, clinical characteristics, and treatment patterns in early breast cancer (eBC) in Greece.

Study Design: This non-interventional, observational study will include data analysis of approximately 2000 eBC patients and genomic profile analysis of 300 HR+/HER2- patients using the PRIME-Dx platform.

Study Objectives: The primary objective is to describe patient demographics and clinical characteristics, while the exploratory objective is to test the hypothesis that endocrine resistance molecular subtypes predict early recurrence in HR+/HER2- eBC patients.

Statistical Analysis: The study will use descriptive statistics to present continuous and categorical variables, and time-to-event analyses for recurrence-free survival (RFS) and breast cancer-free interval (BCFi).

Pharmacovigilance Requirements: The collaboration partner, as the regulatory sponsor, is responsible for meeting safety reporting requirements to Novartis

and health authorities.

Study status

Ongoing

Research institutions and networks

Institutions

European Interbalkan Medical Center (EIMC)

Greece

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Institution **Hospital/Clinic/Other health care facility**

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Konstantinos Papazisis

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 24/09/2024

Actual: 10/10/2024

Study start date
Actual: 16/10/2024

Data analysis start date
Planned: 21/10/2024

Date of interim report, if expected
Planned: 21/10/2025

Date of final study report
Planned: 30/09/2028

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Novartis Hellas SACI, Research Collaboration in Breast Cancer

Study protocol

NIS PDC_Breast Cancer_SONATA RC_Protocol synopisis.pdf(374.02 KB)

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Other

Data collection methods:

Combined primary data collection and secondary use of data

Study design:

This non-interventional, observational study will include data analysis of approximately 2000 eBC patients and genomic profile analysis of 300 HR+/HER2- patients using the PRIME-Dx platform.

Main study objective:

The study aims to describe patient demographics, clinical characteristics, and treatment patterns in early breast cancer (eBC) in Greece.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

This is a non-interventional, observational, single-center, primary data collection study, which will include a representative sample of outpatients diagnosed with early Breast Cancer (eBC) in Northern Greece. The collaborator holds a database of eBC patients (~2000 patients up to date) and of good quality. The collaborator is also performing genomic profile analysis for various mutations as part of his clinical practice. Data will be retrieved from the electronic patient database owned by the collaborator.

Study drug and medical condition

Medical condition to be studied

Breast cancer

Population studied

Age groups

Adult and elderly population (≥18 years)

Adults (18 to < 65 years)

Elderly (≥ 65 years)

Study design details

Data analysis plan

The study will use descriptive statistics to present continuous and categorical variables, and time-to-event analyses for recurrence-free survival (RFS) and breast cancer-free interval (BCFi).

Data management

ENCePP Seal

> The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data sources (types)

Electronic healthcare records (EHR)

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No