

Nationwide analysis of the breast cancer guidelines adherence in Bulgaria

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Study

Finalised

Administrative details

EU PAS number

EUPAS1000000571

Study ID

1000000571

DARWIN EU® study

No

Study countries

Bulgaria

Study description

Real-World Data Analysis of Breast Cancer Guidelines Adherence Using Danny Platform

Study status

Finalised

Research institutions and networks

Institutions

Sqilline Health

Bulgaria

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Institution

Non-Pharmaceutical company

Medical University - Pleven, Bulgaria

Contact details

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Primary lead investigator

Dobromir Dimitrov

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 18/09/2023

Actual: 18/09/2023

Study start date

Planned: 01/01/2019

Actual: 01/01/2019

Date of final study report

Planned: 16/04/2024

Actual: 24/04/2024

Sources of funding

- No external funding

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Other study registration identification numbers and links

[Nationwide Analysis of Breast Cancer Guidelines Adherence in Bulgaria](#)

Methodological aspects

Study topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Other

If 'other', further details on the scope of the study

Nationwide analyses of breast cancer

Data collection methods:

Secondary use of data

Study design:

Assess adherence to breast cancer diagnostic and treatment guidelines in Bulgaria using RWD processed and analyzed by Danny Platform.

Main study objective:

Evaluate the utilization rates of core-needle biopsy, frozen section, breast-conserving surgery, and sentinel lymph node biopsy.

Identify challenges and opportunities for improving adherence to international guidelines in Bulgaria.

Study Design

Non-interventional study design

Cohort

Population studied

Short description of the study population

Data from January 2019 to August 2023 nationwide was analyzed using the platform with access to anonymized medical information from Bulgaria's leading territorial oncology hospitals. A total of 13,790 patients met the inclusion criteria.

Age groups

- **In utero**
- **Paediatric Population (< 18 years)**
 - Neonate
 - Preterm newborn infants (0 - 27 days)
 - Term newborn infants (0 - 27 days)
 - Infants and toddlers (28 days - 23 months)
 - Children (2 to < 12 years)
 - Adolescents (12 to < 18 years)
- **Adult and elderly population (≥18 years)**
 - Adults (18 to < 65 years)
 - Adults (18 to < 46 years)
 - Adults (46 to < 65 years)
 - Elderly (≥ 65 years)
 - Adults (65 to < 75 years)
 - Adults (75 to < 85 years)
 - Adults (85 years and over)

Study design details

Summary results

The analysis revealed suboptimal adherence to breast cancer diagnostic and treatment guidelines in Bulgaria.

Low utilization of core-needle biopsy (CNB), high reliance on frozen sections, and below-average rates of breast-conserving surgery and sentinel lymph node biopsy were observed.

The gold standard diagnostic tool, CNB, was done in 5,427 patients (39.35%), an intraoperative frozen section was performed as a method for confirmation of breast cancer in 6,257 patients (45.37%) and the standard technique for lymph node evaluation, sentinel lymph node biopsy, was done in 357 patients (2.99%). These findings highlight the need for targeted interventions to improve guideline adherence and patient outcomes in Bulgaria.

Documents

Study report

[Nationwide analysis of the breast cancer guidelines adherence in Bulgaria_ScienceDirect_1.pdf](#) (477.65 KB)

Study publications

[Nationwide Analysis of Breast Cancer Guidelines Adherence in Bulgaria](#)

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 source(s)

Danny Platform

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Yes

Check completeness

Yes

Check stability

Yes

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

Not applicable