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Can we predict advanced lymph node disease and safely avoid sentinel lymph node biopsy in early breast cancer? A nationwide study using Swedish registry data

Submission date
28/04/2026

Recruitment status
No longer recruiting

Registration date
28/04/2026

Overall study status
Completed

Last Edited
28/04/2026

Condition category
Cancer

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

Plain English summary of protocol

Background and study aims
Sentinel lymph node biopsy is a minor surgical procedure used to check whether breast cancer has spread to the lymph nodes in the armpit. Current guidelines suggest that some women with small, low-risk breast cancers may safely avoid this procedure. However, many patients still undergo sentinel lymph node biopsy because clinicians are concerned about missing more advanced lymph node disease, which can affect decisions about further treatment.
This study aims to develop and test a model to predict which patients have advanced lymph node disease (defined as cancer spread to four or more lymph nodes) without needing this procedure.

Who can participate?
This study includes women with early breast cancer recorded in the Swedish National Quality Registry for Breast Cancer. All participants are postmenopausal, aged 50 years or older, and have small, low-risk tumours. The cancer has not been found to have spread to the lymph nodes based on routine clinical assessment. These patients meet current guideline criteria for possibly avoiding sentinel lymph node biopsy.

What does the study involve?
This is a registry-based study using existing patient data. No new tests or treatments will be performed. Researchers will use information such as tumour size and other tumour and clinical characteristics to develop a prediction model. The data will be divided into two groups: one to develop the model and one to test how well it works.

What are the possible benefits and risks of participating?
There are no direct risks or benefits for the individuals included, as the study uses existing data only. The results may help improve future care by reducing unnecessary surgery and supporting more personalised treatment decisions.

Where is the study run from?
The study is conducted at Lund University and Skåne University Hospital in Sweden, using nationwide registry data.

When is the study starting and how long is it expected to run for?
The study uses data collected between January 2014 and December 2023. The analysis is ongoing and is expected to be completed in 2026.

Who is funding the study?
The study is funded by Swedish governmental funding of clinical research (ALF), the Swedish Research Council, Cancerfonden, and Lund University.

Who is the main contact?
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Contact information

Type(s)
Scientific, Principal investigator, Public

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Study information

Scientific Title
Predicting advanced nodal disease (≥pN2) without sentinel lymph node biopsy in early breast cancer: a nationwide real-world data cohort study

Study objectives
To develop and validate a preoperative prediction model to estimate the individual probability of high nodal burden, defined as ≥pN2 disease, in patients with early breast cancer who meet American Society of Clinical Oncology (ASCO) criteria for omission of sentinel lymph node biopsy.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 06/05/2014, Swedish Ethical Review Authority (Etikprövningsmyndigheten Box 2110, Uppsala, 750 02, Sweden; +46 (0)10-475 08 00; registrator@etikprovning.se), ref: 2024-02690-02

Primary study design
Observational

Secondary study design
Cohort study

Study type(s)

Health condition(s) or problem(s) studied
High nodal burden (≥pN2, ≥4 positive axillary lymph nodes) early breast cancer

Interventions
This is a retrospective nationwide registry-based cohort study using data from the Swedish National Quality Registry for Breast Cancer. Eligible patients are women with early breast cancer diagnosed between 2014 and 2023 who meet criteria for possible omission of sentinel lymph node biopsy. The cohort will be divided into training and test sets based on year of diagnosis. Candidate clinical and tumour-related predictors available before or around surgery will be evaluated; no imaging or sentinel lymph node biopsy data. Alongside descriptive results, a prediction model will be developed and validated to estimate the probability of high nodal burden.

Intervention Type
Other

Primary outcome(s)
1. High nodal burden (≥pN2 disease) measured using pathological nodal status, defined as ≥pN2 disease, corresponding to ≥4 positive axillary lymph nodes. Nodal counts are based on sentinel lymph node biopsy and/or axillary lymph node dissection data recorded in the Swedish National Quality Registry for Breast Cancer; at primary breast cancer surgery and axillary staging

Key secondary outcome(s))
1. Overall survival measured using time from primary breast cancer diagnosis to death from any cause, obtained from registry linkage, at date of diagnosis until date of data extraction (end of follow-up)

Completion date
20/04/2026

Eligibility

Key inclusion criteria
1. Female sex
2. Invasive breast cancer
3. ≤2 cm
4. Clinically node negative
5. Postmenopausal status

6. Aged ≥50 years
7. Unifocal tumour
8. Invasive ductal carcinoma
9. Nottingham histological grade 1-2
10. Oestrogen receptor–positive tumour
11. Human epidermal growth factor receptor 2-negative tumour
12. Planned upfront breast surgery

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
50 years

Upper age limit
100 years

Sex
Female

Total final enrolment
13211

Key exclusion criteria
1. No data on endpoint variable
2. Age <50 years
3. Pre- or perimenopausal status
4. Tumour size T2–T4
5. Clinically node-positive disease
6. Distant metastatic disease
7. Multifocal disease
8. Non-invasive tumour
9. Not classified as no specific type histology
10. Nottingham histological grade 3
11. Oestrogen receptor–negative tumour
12. HER2-positive tumour

Date of first enrolment
01/01/2014

Date of final enrolment
31/12/2023

Locations

Countries of recruitment
Sweden

Sponsor information

Organisation
Lund University

ROR
https://ror.org/012a77v79

Funder(s)

Funder type

Funder Name
Lunds Universitet

Alternative Name(s)
Lund University, Universitas Lundensis, Universitas Gothorum Carolina, Royal Caroline Academy, Regia Academia Carolina, Lund University | Lund, Sweden | LU, Lunds universitet, LU

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Sweden

Funder Name
The Governmental Funding of Clinical Research within the National Health Services ,Sweden

Funder Name
Vetenskapsrådet

Alternative Name(s)
Swedish Research Council, VR

Funding Body Type
Government organisation

Funding Body Subtype

National government

Location
Sweden

Funder Name
Cancerfonden

Alternative Name(s)
Swedish Cancer Society

Funding Body Type
Private sector organisation

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

Location
Sweden

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Statistical Analysis Plan			28/04/2026	No	No