

Construction and validation of axillary lymph node metastasis prediction model for breast cancer

Submission date 25/02/2024	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 27/02/2024	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 07/07/2025	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Assessing axillary lymph node metastasis status and staging is crucial, but the accuracy of conventional clinical assessment methods is unsatisfactory. The researchers propose combining radiomics technology (to extract quantitative, and ideally reproducible, information from diagnostic images), machine learning algorithms and 3D visualization technology to construct a 3D visualization diagnosis and localization methods for axillary lymph nodes. This provides a new method for clinical axillary lymph node assessment of breast cancer.

Who can participate?

Female invasive breast cancer patients aged between 20-85 years old who had completed lung-enhanced CT and axillary lymph node dissection surgery.

What does the study involve?

Data will be retrospectively collected from all enrolled patients who underwent high-resolution thin-section enhanced CT of the lungs within 1 month before surgery. All patients had complete clinicopathological data, did not have distant metastases, and had not undergone neoadjuvant therapy (NAT).

What are the possible benefits and risks of participating?

A 3D visualization diagnosis and localization method will be constructed, which can effectively improve the predictive efficacy of assessing axillary lymph node status. Using medical records obtained from previous clinical visits for the study is consistent with minimal risk and will not adversely affect the rights or health of the participants.

Where is the study run from?

The Second Xiangya Hospital of Central South University.

When is the study starting and how long is it expected to run for?

January 2016 to January 2024

Who is funding the study?

The Science and Technology Innovation Program of Hunan Province (Grant No.2021SK2026).

Who is the main contact?

Prof. Wenjun Yi, yiwenjun@csu.edu.cn.

Contact information

Type(s)

Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Protocol serial number

Nil known

Study information

Scientific Title

Construction and application of three-dimensional visualization diagnosis method for axillary lymph nodes of breast cancer

Study objectives

Assessing axillary lymph node metastasis status and staging is crucial, but the accuracy of conventional clinical assessment methods is unsatisfactory. It is proposed that combining radiomics technology, machine learning algorithms and 3D visualization technology to construct 3D visualization diagnosis and localization methods for axillary lymph nodes. This provides a new method for clinical axillary lymph node assessment of breast cancer.

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 28/03/2023, Clinical Research Ethics Committee, The Second Xiangya Hospital, Central South University (The Second Xiangya Hospital of Central South University, No. 139, Renmin Central Road, Changsha, 410011, China; +861 0731-85292476; xy2gcpduan@163.com), ref: LYF2023043

Study design

Single-center diagnostic test

Primary study design

Observational

Study type(s)

Diagnostic

Health condition(s) or problem(s) studied

Prediction of axillary lymph node metastasis in breast cancer patients

Interventions

Researchers will retrospectively collect data from invasive breast cancer patients who had completed lung-enhanced CT and axillary lymph node surgery. The researchers will construct a 3D axillary lymph node atlas using 3D visualization techniques. Researchers will localize and segment regions of interest (ROIs) from axillary lymph nodes, extract and select radiomic features, and construct axillary lymph node prediction models.

Intervention Type

Other

Primary outcome(s)

Predicting correct classification rate, sensitivity and specificity after axillary surgery measured using 3D visualization techniques to construct predictive models at one time point

Key secondary outcome(s)

Predicting misclassification rate, false-positive rate and false-negative rate after axillary surgery measured using 3D visualization techniques to construct predictive models at one time point

Completion date

31/01/2024

Eligibility

Key inclusion criteria

1. Underwent BC surgery at our hospital with postoperative pathology confirming invasive BC
2. Underwent axillary lymph node dissection (ALND) at our hospital
3. Completed a high-resolution, thin-section enhanced CT scan of the lung in our radiology department within one month before surgery
4. Had complete clinicopathological data

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

20 years

Upper age limit

85 years

Sex

Female

Total final enrolment

500

Key exclusion criteria

1. Had bilateral primary or metastatic bc
2. Received neoadjuvant therapy (nat) before surgery
3. Had incomplete or poor-quality CT scans, flat scans only, or scans conducted externally
4. Had distant metastatic lesions or concurrent other malignancies

Date of first enrolment

29/03/2023

Date of final enrolment

31/12/2023

Locations

Countries of recruitment

China

Study participating centre

The Second Xiangya Hospital of Central South University

No. 139, Renmin Central Road

Changsha

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410011

Sponsor information

Organisation

Hunan Provincial Science and Technology Department

ROR

<https://ror.org/04qgr7x96>

Funder(s)

Funder type

Not defined

Funder Name

Science and Technology Program of Hunan Province

Alternative Name(s)

Science and Technology Project of Hunan Province, Hunan Provincial Science and Technology Plan Project, Hunan Provincial Science and Technology Project Foundation, Hunan Science and Technology Innovation Project, Science and Technology Plan Project of Hunan Province, Hunan Provincial Natural Science and Technology Major Project, Major Science and Technology Program of Hunan province,

Funding Body Type

Government organisation

Funding Body Subtype

Local government

Location

China

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study will be published as a supplement to the results publication

IPD sharing plan summary

Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/09/2024	25/04/2025	Yes	No
Results article		24/06/2025	07/07/2025	Yes	No