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

Submission date
25/02/2024

Recruitment status
No longer recruiting

Registration date
27/02/2024

Overall study status
Completed

Last Edited
07/07/2025

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

ClinicalTrials.gov (NCT)
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
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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

Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes