

Preoperative prediction of axillary lymph node burden in early-stage invasive breast cancer

Submission date 22/06/2024	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 26/06/2024	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 26/06/2024	Condition category Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

This study aims to use radiomics features extracted from preoperative breast MRI combining clinical and histological features to construct a prediction model for evaluating axillary lymph node (ALN) metastasis burden in patients with early-stage (T1-2) breast cancer. The study methodology provides a noninvasive and practical way of preoperatively predicting the extent of ALN involvement in early-stage (T1-2) breast cancer patients. It has the potential to tailor appropriate axillary treatment options for patients with early-stage breast cancer towards less invasive surgical practices.

Who can participate?

Patients aged 18 to 85 years old with early-stage invasive breast cancer

What does the study involve?

This study will look back through a database to find breast MRI images that fit specific criteria. People whose MRI scans are selected will be included in the study without needing to give consent again. They will have had a pre-scheduled breast MRI with a special contrast dye before any surgery, and no other tests will be required. The study will follow these participants from the time their images are taken until the study ends.

The goal is to create and test a model that can predict certain outcomes. Eighty patients with early-stage breast cancer will be included, with 56 in the training group and 24 in the testing group. The study will analyze features from their MRI images using a semi-automated process and consider their clinical and pathological information. A predictive model will be built using a machine learning technique called support vector machines.

What are the possible benefits and risks of participating?

The benefits include early prediction of axillary lymph node involvement, noninvasive assessment, personalized treatment planning and contribution to research.

The risks include data privacy concerns, inconvenience, potential for false positives/negatives and unknown long-term implications.

Where is the study run from?
Chang Gung Memorial Hospital Chiayi Branch, Taiwan

When is the study starting and how long is it expected to run for?
March 2023 to May 2024

Who is funding the study?
Chang Gung Memorial Hospital, Taiwan

Who is the main contact?
Shu-Tian Chen, stchen0909@gmail.com

Contact information

Type(s)

Public, Scientific, Principal investigator

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

Chang Gung Memorial Hospital funding number: CMRPG6N0071

Study information

Scientific Title

Preoperative prediction of axillary lymph node burden in early-stage invasive breast cancer with clinical-pathology and MRI-based radiomics

Study objectives

Using radiomics features extracted from preoperative breast MRI combining clinicohistologic features may help to preoperatively predict axillary lymph node burden on breast cancer patients.

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 28/03/2023, Chang Gung Medical Foundation Human Experiment Ethics Committee (199, Tung Hwa North Road, Taipei, 105, Taiwan; +886 (03) 3196200; lrb1@cgmh.org.tw), ref: 202201772B0C501

Study design

Single-center retrospective study

Primary study design

Observational

Study type(s)

Diagnostic

Health condition(s) or problem(s) studied

Early stage breast cancer patients

Interventions

This study will retrospectively search a database to identify breast MRI images that meet specific inclusion and exclusion criteria. Owners of the selected breast MRI scans will be enrolled in the study with informed consent waived. Participants will undergo scheduled pre-operative staging dynamic contrast-enhanced breast MRI, with no additional studies required. The observation and follow-up periods will extend from the time of image acquisition until the conclusion of the study. The study aims to develop and validate a predictive model by enrolling eighty patients with early-stage breast cancer, divided into a training set (56 patients) and a validation set (24 patients). Radiomics features will be extracted from dynamic contrast-enhanced MRI images after semiautomated segmentation, and clinical-pathologic features will also be considered. Binary radiomics prediction models will be built using a support vector machines classifier.

Intervention Type

Other

Primary outcome(s)

Axillary lymph node burden prediction measured using the model prediction and MRI pathology reports after the axillary surgery at one timepoint

Key secondary outcome(s)

Performance comparison measures using the prediction model and by a radiologist after the axillary surgery at one timepoint

Completion date

31/05/2024

Eligibility

Key inclusion criteria

1. Invasive breast carcinoma confirmed by biopsy
2. Early-stage (clinical stage T1-2)
3. Underwent DCE-MRI examination one week before surgery
4. All patients who received axillary surgery either SLNB or ALND

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

18 years

Upper age limit

85 years

Sex

Female

Total final enrolment

80

Key exclusion criteria

1. Non-primary breast cancer or carcinoma in situ-only lesions
2. Excision biopsy before DCE-MRI examination
3. Pre-operative neoadjuvant therapy
4. Incomplete clinical data

Date of first enrolment

01/05/2023

Date of final enrolment

30/04/2024

Locations

Countries of recruitment

Taiwan

Study participating centre

Chang Gung Memorial Hospital Chiayi Branch
No.6, Chia-Pu Road, West section
Chiayi County
Taiwan
61363

Sponsor information

Organisation

Chiayi Chang Gung Memorial Hospital

ROR

<https://ror.org/04gy6pv35>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Chiayi Chang Gung Memorial Hospital

Alternative Name(s)

Chia-Yi Chang-Gong Memorial Hospital, Chang Gung Memorial Hospital, Chia-Yi

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

Taiwan

Results and Publications

Individual participant data (IPD) sharing plan

The data sharing plans for current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date