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

Submission date 22/06/2024	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 26/06/2024	**Overall study status** Completed	
Last Edited 26/06/2024	**Condition category** Cancer	

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?
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Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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; Irb1@cgmh.org.tw), ref: 202201772B0C501

Study design
Single-center retrospective study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Medical and other records

Study type(s)
Diagnostic

Participant information sheet
No participant information sheet available

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 measure

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

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

Overall study start date
28/03/2023

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

Age group
Mixed

Lower age limit
18 Years

Upper age limit
85 Years

Sex
Female

Target number of participants
200

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

Sponsor details
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Sponsor type
Hospital/treatment centre

Website
https://www.cgmh.org.tw/branch/branch_jia.htm

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

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date
30/05/2025

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