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Axillary assessment in breast cancer patients

Submission date
26/02/2023

Recruitment status
No longer recruiting

Registration date
14/03/2023

Overall study status
Completed

Last Edited
14/11/2023

Condition category
Cancer

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Axillary lymph node metastasis is one of the most significant indicators of overall recurrence and long-term survival in breast cancer patients. The 5-year survival rate for individuals with breast-confined disease ranges from 90 to 99%, but it falls to 85% for those with regional lymph node metastases. Therefore, a correct evaluation of axillary lymph node status is important for staging breast cancer and choosing the best treatment. Sonography can detect metastatic lymph nodes with varying degrees of sensitivity and specificity, while its routine use in the preoperative assessment of axillary lymph nodes remains controversial. The aim of this study is to assess the diagnostic accuracy of pretreatment axillary sonography in a clinical setting in Iraq and to determine whether a sonographic evaluation of the axilla as a tool for the regional staging of breast cancer should be routinely performed in all cases.

Who can participate?
Adult women with histologically confirmed breast cancer

What does the study involve?
Axillary ultrasound (US) will be performed on all patients to assess lymph node status using certain dimensional and morphological parameters. These criteria will be recorded in the checklist designed for this study. The axillary US could be positive or negative. US will be considered positive when an abnormal node with at least one suspicious finding will be found, and US will be considered negative when there are non-visualized or non-suspicious nodes. US-guided fine-needle aspiration biopsy will be done on all patients with positive axillary US results. Patients with negative axillary US results will have a sentinel lymph node biopsy. The US findings will be compared to the histopathology results.

What are the possible benefits and risks of participating?
The study benefits the participants in deciding on further management. There is no risk from a US examination and the risk of biopsy taking can be reduced by performing the procedure by expert doctors at the hospital.

Where is the study run from?
Rizgary Teaching Hospital and the Department of Surgery, College of Medicine, Hawler Medical University (Iraq)

When is the study starting and how long is it expected to run for?
August 2021 to January 2023

Who is funding the study?
Hawler Medical University (Iraq)

Who is the main contact?
Dr Shawnam Nasih Dawood, shawnm.nasih@hmu.edu.krd (Iraq)

Contact information

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Sonographic evaluation of axillary lymph node status in newly diagnosed breast cancer patients: A prospective study

Study objectives
Sonography can detect metastatic lymph nodes with varying degrees of sensitivity and specificity, while its routine use in the preoperative assessment of axillary lymph nodes remains controversial.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 01/09/2021, Research Ethics Committee of The College of Medicine / Hawler Medical University (College of Medicine, Khanzad Street, Erbil, Kurdistan Region, Iraq; +964 66 222 7275; medicine@hmu.edu.krd), ref: none available

Study design
Prospective diagnostic accuracy study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)

Hospital, University/medical school/dental school

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Axillary assessment in breast cancer patients

Interventions
Accuracy of axillary ultrasound (US) in diagnosing metastatic lymph nodes in breast cancer patients

US will be performed on breast cancer patients to assess lymph node status using predetermined criteria, which include the presence of any breast lesion and its features, location, and dimensions. Correct evaluation of axillary lymph node status is important for staging breast cancer and choosing the best treatment, sonography is an easy non-invasive, cost-effective method to assess the axillary lymph nodes.

The study participants are women with histologically confirmed breast cancer.

Procedures: Following a hand-held whole-breast US examination, axillary US is performed using linear 7–12 MHz transducers. The procedure is explained to the patients, and a nurse will position the patients. Both breasts are examined in orthogonal planes, and the presence of any breast lesion and its features, location, and dimensions are documented. The scanning of the axilla starts from the lowest part and continued upward toward the axillary fossa. Both axillae are examined for the presence of nodes and the features of any detected nodes, such as level, number, size, overall shape, margin, assessment of the cortex and hilum, and lymph node vascularity. The following lymph node criteria are regarded as suspicious: round or irregular shape; lobulated or irregular margin; cortical changes, such as diffuse cortical thickness ≥ 3 mm, focal cortical thickness ≥ 3 mm, or markedly hypoechoic cortex; and sinus changes, such as displacement or total replacement, in addition to nonhilar blood flow displayed by color Doppler sonography. Then, these dimensional and morphological criteria are recorded. The axillary US could be positive or negative. US is considered positive when an abnormal node with at least one suspicious finding is found, and US is considered negative in cases of nonvisualized or nonsuspicious nodes. US-guided fine needle aspiration biopsy (FNAB) is done on all patients with positive axillary US results. Under completely aseptic conditions, a local anesthetic (lidocaine) is applied to the skin. The dominant lymph node is identified under US guidance, and then aspiration is achieved by capillarity using a 23- or 25-gauge needle and a 5-cc syringe. Enough aspirates are obtained to prepare two slides, which then had fixed with 95.6% ethanol, the specimen then sent for cytological examination.

Expert breast radiologists with more than five years in breast imaging and fellowship in breast radiology performed the US examination and the US-guided FNAB.

Face-to-face intervention and each patient will be examined alone in the presence of a nurse and a radiologist. All the procedures took place at the hospital.

The US examination is performed only once, took only a few minutes, and caused no discomfort to the patient, except for exposing the axillary region to the cold, which is ameliorated by a proper room temperature. Additionally, the gel used for the examination could be easily removed by napkins.
Patients with negative FNAB and axillary ultrasound results had a sentinel lymph node biopsy (SLNB). As standard care for breast cancer patients, SLNB is performed by specialist breast surgeons on the day of the operation. Patients with metastatic lymph nodes on frozen sections routinely underwent immediate axillary surgery during the study period, with no further axillary interference for sentinel lymph node-negative patients.

Modifications: The procedure went according to the protocol.

Planned: All US examinations are real-time and the performing radiologist can adjust the examination during the procedure. Patient data, including age; tumor characteristics, such as tumor size, location, type, grade, and focality; sonographic axillary status; and pathology findings are reviewed and analyzed. The diagnostic accuracy of preoperative axillary US and the performance of US criteria for diagnosing metastatic lymph nodes are studied. IBM SPSS Statistics, Version 25.0, is used for all statistical analyses (IBM Corp.). P values less than 0.05 are considered statistically significant.

Intervention Type
Other

Primary outcome measure
Evidence of any breast lesion and its features, location, and dimensions measured using ultrasound versus histopathology at one timepoint

Secondary outcome measures
Accuracy (sensitivity, specificity, positive predictive value, negative predictive value) of diagnosing metastatic lymph nodes measured using axillary ultrasound at one timepoint

Overall study start date
22/08/2021

Completion date
01/01/2023

Eligibility

Key inclusion criteria
Women with histologically confirmed breast cancer

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
200

Total final enrolment
180

Key exclusion criteria
1. A prior diagnosis of breast cancer who had undergone any type of neoadjuvant treatment or surgical procedure
2. Breast cancer patients planned for neoadjuvant chemotherapy
3. History of lymphoma or other malignancies
4. Pregnancy or breastfeeding

Date of first enrolment
01/09/2021

Date of final enrolment
01/12/2022

Locations

Countries of recruitment
Iraq

Study participating centre
Rizgary Teaching Hospital
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Study participating centre
Erbil Breast Center
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Funder(s)

Funder type
University/education

Funder Name
Hawler Medical University

Results and Publications

Publication and dissemination plan
Planned publication in an open-access peer-reviewed journal

Intention to publish date
01/11/2023

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be available upon request from the author: Dr Shawnam Nasih Dawood, shawnm.nasih@hmu.edu.krd

The type of data that will be shared: All of the individual participant's data collected during the trial, after deidentification.
Timing for availability: Immediately following publication. No end date.
Whether consent from participants was required and obtained: Participant consent was required and obtained
Comments on data anonymization: No names, photos or any other personal information were included
Any ethical or legal restrictions: Not applicable

Any additional comments: Please note that this study is part of the trialist's ongoing PhD requirements and the cases were selected from the thesis under the title of Mammography, Sonography, and Magnetic Resonance Imaging in Breast Cancer Disease: A Comparative Study

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Preprint results		20/02/2023	14/11/2023	No	No