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A study of a new ultrasound scan to check if breast lumps are safe or risky

Submission date
08/09/2025

Recruitment status
No longer recruiting

Registration date
17/09/2025

Overall study status
Completed

Last Edited
16/09/2025

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[X] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
This study is looking at a new way to help doctors decide whether a lump in the breast might be cancerous. Right now, ultrasound scans are commonly used, but they don't always give a clear answer. The researchers are testing a technique called "elastography," which measures how stiff the lump is. Stiffer lumps are more likely to be cancerous. The aim is to see if elastography can improve diagnosis and reduce unnecessary biopsies.

Who can participate?
Women who have been found to have a breast lump that looks uncertain (but not highly suspicious) on a regular ultrasound scan—specifically those classified as BI-RADS 3 or 4a—may be invited to take part.

What does the study involve?
If you agree to take part, a trained sonographer will perform an additional scan using elastography. This scan is painless and non-invasive. Afterwards, you'll have a core needle biopsy, which is the standard way to check if a lump is cancerous. The results from the scans and biopsies will be compared, but the people doing each test won't know the results of the other to keep things fair.

What are the possible benefits and risks of participating?
There's no direct benefit to you, but your participation could help improve how breast lumps are diagnosed in the future. The elastography scan is safe and non-invasive. The biopsy is a routine procedure, but like any medical test, it carries small risks such as bruising or infection.

Where is the study run from?
Erbil breast center (Iraq)

When is the study starting and how long is it expected to run for?
July 2024 to July 2025

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Nasik Majeed, drnasik21@gmail.com

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Study information

Scientific Title
Diagnostic Accuracy of Sound Touch Elastography Versus Conventional Ultrasound in BI-RADS 3 and 4a Breast Masses

Study objectives
The objective of this study is to evaluate the role of sound touch elastography, quantification, and shear ratio in breast mass classification. It assesses whether incorporating them into ultrasound for BI-RADS 3 and 4a masses can improve category upgradation or down-gradation.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 06/08/2025, Research Ethics Committee (College of medicine- Hawler medical university- Khanzad street, Erbil, -, Iraq; +964 7507791292; ruqaya.taher@hmu.edu.krd), ref: 11

Primary study design
Observational

Study design
Prospective diagnostic accuracy study

Study type(s)

Diagnostic

Health condition(s) or problem(s) studied
Patients with breast masses, BIRADS 3 and 4

Interventions
Patient eligibility verified, informed consent obtained, demographics and clinical history recorded, and clinical breast exam performed. Conventional ultrasound with BI-RADS assessment done, we selected BI RADS 3 and 4a breast masses for our study and further assessment by Sound Touch elastography for the mass and shell, recording quantitative metrics (Emax, Emean, STQ), and shear ratio (lesion-to-fat).
The data saved and completed questionnairre form. (Total time for imaging session: ~30–60 minutes.)
If BI-RADS 4a: we arranged ultrasound-guided core-needle biopsy within 7 days. .
If BI-RADS 3: ultrasound-guided core-needle biopsy arranged for patients with positive family history of breast cancer, on surgeon's request, or on request of health-concious patients
The histopathology result (returned within 7–14 days) for the final diagnosis

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Breast masses assessed using a single measurement of ultrasonography, as well as a separate singular measurement using elastography
2. Additional information collected through a questionnaire detailing the patient’s medical history

Key secondary outcome(s)
There are no secondary outcome measures

Completion date
25/07/2025

Eligibility

Key inclusion criteria
Patients with BIRADS 3 and 4 breast masses with sizes between 5-30 mm

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
17 Years

Upper age limit
70 Years

Sex
Female

Total final enrolment
133

Key exclusion criteria
1. Masses less than 5 mm and larger than 30 mm
2. Refused biopsy
3. Pregnant or lactating women
4. Breast with implant or scar
5. Masses stable for more than one year

Date of first enrolment
05/10/2024

Date of final enrolment
10/07/2025

Locations

Countries of recruitment
Iraq

Study participating centre
Erbil breast center
40 m street beside Cihan Bank
Erbil
Iraq
-

Sponsor information

Organisation
Hawler Medical University

ROR
https://ror.org/02a6g3h39

Funder(s)

Funder type
Other

Funder Name
investigator initiated and Funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publicly available repository (see study outputs)

IPD sharing plan summary
Stored in publicly available repository, Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Dataset	SAPP sav file		15/09/2025	No	No
Dataset	zip file of docx files. Questionnaires		15/09/2025	No	No