

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 17/09/2025	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 16/09/2025	Condition category Cancer	<input checked="" type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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

Contact name

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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

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

Study design

Prospective diagnostic accuracy study

Primary study design

Observational

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 questionnaire 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-conscious 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

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