

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jun 2026

Comparative study of breast mass evaluation by a new diagnostic method (Breast Light) and mammography in women over forty years

Protocol summary

Study aim

Determining the diagnostic value of the new device (Breast Light) in comparison with mammography for evaluating breast masses

Design

The present study is one of the studies evaluating diagnostic tests and screening. All eligible people (including 252 people) will be examined with both Brestlight and mammography diagnostics based on available sampling. Clearly, blinding and randomization do not apply in this study.

Settings and conduct

In this study, 252 women over the age of 40 who are candidates for breast cancer screening or who have symptoms such as mastalgia, nipple discharge, changes in the appearance of the breast, etc., according to the doctor, need to be screened for diagnostic methods. Initially, the specialist will evaluate the breast tissue using a burst light device in a dark room through direct contact of the probe with the skin of the person. Seeing the dark areas of the cluster indicates malignancy and the results will be recorded by the specialist. They should then be re-examined with a mammogram. It should be noted that in people who will be diagnosed with the disease will be directed to continue treatment and biopsy.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Women 40 years of age and older, women candidates for breast cancer screening
Exclusion criteria: Reluctance to undergo screening with Brest Light, pregnancy

Intervention groups

In this study, two diagnostic interventions, Brest Light and mammography, will be used to evaluate breast masses. In this way, all the subjects will be examined first using the new Brest Light diagnostic method, and then mammography will be performed

Main outcome variables

Primary outcome variables include true positive, true

negative, false positive, and false negative of the diagnostic test Brest Light

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090701002114N8**

Registration date: **2021-01-13, 1399/10/24**

Registration timing: **prospective**

Last update: **2021-01-13, 1399/10/24**

Update count: **0**

Registration date

2021-01-13, 1399/10/24

Registrant information

Name

Fatemeh Yari

Name of organization / entity

Lorestan university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 66 1222 6450

Email address

yari.f@lums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-01-19, 1399/10/30

Expected recruitment end date

2021-06-21, 1400/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparative study of breast mass evaluation by a new diagnostic method (Brest Light) and mammography in women over forty years

Public title
Evaluation of breast mass diagnosis with breast light and mammography

Purpose
Screening

Inclusion/Exclusion criteria
Inclusion criteria:
Women aged 40 and over Women who are candidates for breast cancer screening
Exclusion criteria:
pregnancy Reluctance to perform the screening process by Brest Light

Age
From **40 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **252**
More than 1 sample in each individual
Number of samples in each individual: **2**
Each participant is first examined with a Brest Light device and then the same person is examined with a mammogram, so there will be two samples for each person to examine breast masses

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Lorestan University of Medical Sciences

Street address

Office of Research Ethics Committee, Vice Chancellor for Research and Technology of Lorestan University of Medical Sciences, University Campus Complex, km 3 of Khorramabad Boroujerd Road, Khorramabad

City

Khorramabad

Province

Lorestan

Postal code

6813833946

Approval date

2021-01-03, 1399/10/14

Ethics committee reference number

IR.LUMS.REC.1399.258

Health conditions studied

1

Description of health condition studied

Diagnosis and screening of breast mass

ICD-10 code

ICD-10 code description

Breast screening

Primary outcomes

1

Description

The true positive detection rate of the Brest Light device

Timepoint

When using the Brest Light device, and then with a subsequent examination by mammography

Method of measurement

By examining the number of people who are positive for the Brest Light screening test, and these people are diagnosed as really ill with a subsequent examination through mammography and biopsy

2

Description

The true negative detection rate of the Brest Light device

Timepoint

When using the Brest Light device, and then with a subsequent examination by mammography

Method of measurement

By examining the number of people who are negative for the Brest Light screening test, and these people are diagnosed as really health with a subsequent examination through mammography

3

Description

The false positive detection rate of the Brest Light device

Timepoint

When using the Brest Light device, and then with a subsequent examination by mammography

Method of measurement

By examining the number of people who are positive for

the Brest Light screening test, if by the next check by mammography these people are healthy

4

Description

The false negative detection rate of the Brest Light device

Timepoint

When using the Brest Light device, and then with a subsequent examination by mammography

Method of measurement

By examining the number of people who are negative for the Brest Light screening test, if by the next check by mammography these people are ill

Secondary outcomes

1

Description

Brest Light diagnostic sensitivity

Timepoint

When using the Brest Light device, and then with a subsequent examination by mammography

Method of measurement

Divide the number of people who have a positive diagnostic test and are really sick by the number of people who have a positive screening result

2

Description

Brest Light diagnostic specificity

Timepoint

When using the Brest Light device, and then with a subsequent examination by mammography

Method of measurement

Divide the number of people who have a negative diagnostic test and are really healthy by the number of people who have a negative screening result

Intervention groups

1

Description

Intervention group: The first intervention group includes all people for whom the Brest Light diagnostic method is used to examine breast masses.

Category

Diagnosis

2

Description

Intervention group: The second intervention group includes the same people under the first intervention. This time, mammographic diagnostic method will be used to examine breast masses

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Asali hospital

Full name of responsible person

Masoumeh Ghaffarzadeh

Street address

Asali Hospital, 14th Street, Palestine Alley

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Khorramabad

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Lorestan

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6818795895

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+98 66 3340 6099

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asali.hospital@lums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Khoram-Abad University of Medical Sciences

Full name of responsible person

Ibrahim Fallahi

Street address

medical school., 4 km Khorramabad Boroujerd Road., Kamalvand

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falahi.e@lums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Khoram-Abad University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Khoram-Abad University of Medical Sciences

Full name of responsible person
Fatemeh Yari

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Reproductive Health

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Medical school., 4 km Khorramabad Boroujerd Road.,
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Person responsible for scientific inquiries

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Full name of responsible person
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Position
Assistant Professor

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

It is possible to share all the data while maintaining the principle of not mentioning the names of individuals

When the data will become available and for how long

Six months after the publication of the related article

To whom data/document is available

University researchers, gynecologists and radiologists

Under which criteria data/document could be used

The data of the present study can be used for additional research, after obtaining permission and approval from the Vice Chancellor for Research and Technology of Lorestan University of Medical Sciences.

From where data/document is obtainable

Refer to the project manager, Dr. Fatemeh Yari, with email address yari1672@yahoo.com, and contact number 09163613621

What processes are involved for a request to access data/document

After completing the research and publishing the relevant article, individuals can apply to the Vice Chancellor for Research and Technology of Lorestan University of Medical Sciences to receive documents and after obtaining permission from this department, send a confirmation from the Vice Chancellor for Research to the project manager. Can access documentation

Comments