Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 2026

Comparison of simple cyst recurrence following breast FNA in patients with complete evacuation of the cyst and patients with complete evacuation and air injection into the cyst in women

Protocol summary

Summary

The aim of this study was to compare simple cyst recurrence following breast FNA in patients with complete evacuation of the cyst and patients with complete evacuation and air replacement. This study was a single-blind randomized clinical trial. Inclusion criteria: female at the age of 18 years and more; presence of breast simple cyst. Exclusion criteria: history of breast masses (benign or malignant); history of mastectomy and treatment for malignant tumors; cyst's size less than 1 centimeter. Sixty patients with simple breast cyst randomly selected for FNA alone and 60 patients with simple cyst for FNA and air replacement under the guidance of ultrasound. Two groups were matched according to age and size of cysts. All the patient were followed up for 3 months. We record cysts' sizes before procedure and after 3 months. We evaluated cyst recurrence rate after 3 months.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017020720258N32**
Registration date: **2017-03-22, 1396/01/02**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-03-22, 1396/01/02

Registrant information

Name

Fariba Farokhi

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research, Arak University of Medical Sciences

Expected recruitment start date

2015-08-01, 1394/05/10

Expected recruitment end date

2016-12-30, 1395/10/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of simple cyst recurrence following breast FNA in patients with complete evacuation of the cyst and patients with complete evacuation and air injection into the cyst in women

Public title

Treatment of breast's simple cyst

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria: female at the age of 18 years and over; simple cyst. Exclusion criteria: history of breast masses that have been studied (history of benign or malignant); history of mastectomy and other treatments for malignant tumors; cyst's size less than 1 centimeter

Age
No age limit
Gender
Female

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **120**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
Randomize by table of random numbers

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee Arak University Of Medical Sciences
Street address
Dr Mohammad Rafiei, Vice chancellor for research, Payambar Azam complex, Basij squre, Sardasht, Arak
City
Arak
Postal code
38149578558
Approval date
2015-07-27, 1394/05/05
Ethics committee reference number
IR.ARAKMU.REC.1394.104

Health conditions studied

1

Description of health condition studied
Simple cyst breast
ICD-10 code
N60.0
ICD-10 code description
Solitary cyst of breast

Primary outcomes

1

Description
remission rates of cyst
Timepoint
after 3 months
Method of measurement
sonogeraphy

2

Description
Size of cyst
Timepoint
before aspiration and after 3 months
Method of measurement
sonogeraphy

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: 60 patients with simple breast cyst were selected for treatment by FNA alone under the guidance of ultrasound.
Category
Diagnosis

2

Description
Intervention group 2: 60 patients with simple cysts select for treatment by FNA and air replacement under the guidance of ultrasound.
Category
Diagnosis

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam Reza clinic
Full name of responsible person
Dr Fatemeh Safi
Street address
Shahid Shirodi street,Arak
City
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity

Vice chancellor for research, Arak University of Medical Sciences

Full name of responsible person

Dr Mohammad Rafiee

Street address

Vice chancellor for research, Payambar Azam Complex, Basij square, Sardasht, Arak

City

Arak

Grant name

-

Grant code / Reference number

-

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

Yes

Title of funding source

Vice chancellor for research, Arak University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr Fatemeh Safi

Position

Faculty, Radiologist

Other areas of specialty/work

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty