

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jun 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)

##### Phone

+98 86 3222 2003

##### Email address

f.farokhi@arakmu.ac.ir

##### 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 square, 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**

sonography

**2****Description**

Size of cyst

**Timepoint**

before aspiration and after 3 months

**Method of measurement**

sonography

**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**

Arak

**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**

**Street address**

Valiasr Hospital, Valiasr square, Shahid Shirodi street

**City**

Arak

**Postal code**

3814957558

**Phone**

+98 86 3222 2003

**Fax**

+98 863222003

**Email**

safi@arakmu.ac.ir

**Web page address**

-

## Person responsible for scientific 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**

**Street address**

Valiasr Hospital, Valiasr square, Shahid Shirodi street

**City**

Arak

**Postal code**

3814957558

**Phone**

+98 86 3222 2003

**Fax**

+98 863222003

**Email**

safi@arakmu.ac.ir

**Web page address**

-

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Dr Mina Davari

**Position**

resident of radiology

**Other areas of specialty/work**

**Street address**

Complex Payambar azam, Basij square, Sardasht, Arak

**City**

Arak

**Postal code**

3814957558

**Phone**

+98 86 3471 3645

**Fax**

+98 863222003

**Email**

davari@yahoo.com

**Web page address**

-

## 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*