

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

Comparison of the effect of two different doses of ethanol in sclerotherapy for simple skin cysts through skin under ultrasound guidance

Protocol summary

Study aim

Comparison of the efficacy of two different doses of ethanol in sclerotherapy of simple breast cysts

Design

This study is a randomized double-blind clinical trial that is phase 3 of the study in which 70 women with breast cysts are divided into two equal groups by block randomization.

Settings and conduct

This study is a double-blind clinical trial. Patients will be divided into two intervention groups. Then one group will be injected with 99% ethanol equal to 90% cyst volume and the other group 50% cyst volume. Finally, the volume and size of breast cysts in the two groups will be compared after the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Women with simple breast cysts that are 10 mm and larger in size! Age 20-60 years! Lack of treatment of cysts! Satisfaction to participate in the study! Exclusion criteria: Having a history of breast cancer in yourself and first-degree relatives! Pregnancy! Breastfeeding

Intervention groups

Under sterile conditions, a 20 G needle is inserted into the cyst under an ultrasound guide. Most of the cyst volume is aspirated. In one group, 90% of the cyst volume is injected with 99% ethanol without removing the needle, and in the other group, 50% of the remaining volume of 99% ethanol is injected.

Main outcome variables

Cyst volume, largest cyst length, largest cyst width, largest cyst height

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191104045328N11**

Registration date: **2022-06-27, 1401/04/06**

Registration timing: **prospective**

Last update: **2022-06-27, 1401/04/06**

Update count: **0**

Registration date

2022-06-27, 1401/04/06

Registrant information

Name

Amin Haji seyed hoseini

Name of organization / entity

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Iran (Islamic Republic of)

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+98 86 3366 7583

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-06-28, 1401/04/07

Expected recruitment end date

2022-09-29, 1401/07/07

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of two different doses of ethanol in sclerotherapy for simple skin cysts through

skin under ultrasound guidance

Public title

Comparison of the efficacy of two different doses of ethanol in sclerotherapy of simple breast cysts

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Women with simple breast cysts that are 10 mm and larger in size. Age 20-60 years Lack of treatment of cysts Satisfaction to participate in the study

Exclusion criteria:

Having a history of breast cancer in yourself and first-degree relatives Pregnancy Breastfeeding

Age

From **20 years** old to **60 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants are assigned to two intervention and control groups, respectively, based on the randomization sequence that will be generated beforehand. This sequence is unpredictable and its arrangement is completely random. Block randomization method with 8 blocks will be used to allocate samples. Thus, using block numerical random number generation software, a randomization sequence proportional to the sample size required for the two groups will be generated. Initially, all cases in which the two letters A and B can be arranged in blocks of 8 are produced. A block is then randomly selected from the blocks and the layout pattern in that block will be used to assign participants. This block will then be placed in the main container and another block will be selected again. All this will be done with software called Sealed Envelope. With this method, concealment will also be observed. The concept of concealment is to unpredictably assign individuals to groups. In fact, the researcher will not be able to predict which group the next person will be in.

Blinding (investigator's opinion)

Double blinded

Blinding description

In order to blind the resident, the dose of ethanol in the cyst is not known and the ethanols are delivered to the resident in syringes covered with foil and patients are followed up by the resident. Patients are also unaware of the grouping they are in.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Arak University of Medical Sciences

Street address

Research Assistant, Arak University of Medical Sciences, Basij Square, Sardasht, Arak, Iran

City

Arak

Province

Markazi

Postal code

3848176941

Approval date

2021-11-17, 1400/08/26

Ethics committee reference number

IR.ARAKMU.REC.1400.240

Health conditions studied

1

Description of health condition studied

Simple breast cyst

ICD-10 code

N60.0

ICD-10 code description

Solitary cyst of breast

Primary outcomes

1

Description

Breast cyst volume

Timepoint

Before sclerotherapy, three months after sclerotherapy, 6 months after sclerotherapy

Method of measurement

sonography

2

Description

The largest length of a breast cyst

Timepoint

Before sclerotherapy, three months after sclerotherapy, 6 months after sclerotherapy

Method of measurement

sonography

3

Description

The largest width of the breast cyst

Timepoint

Before sclerotherapy, three months after sclerotherapy,
6 months after sclerotherapy

Method of measurement

sonography

4

Description

The largest height of the breast cyst

Timepoint

Before sclerotherapy, three months after sclerotherapy,
6 months after sclerotherapy

Method of measurement

sonography

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: After aspirating the cyst volume in a group, 99% alcohol is injected into the cyst as much as 50% of the cyst volume.

Category

Treatment - Drugs

2

Description

Intervention group: After aspirating the cyst volume in a group, 99% alcohol is injected into the cyst as much as 90% of the cyst volume.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Vali Asr hospital , Arak

Full name of responsible person

Dr Fatemeh Safi

Street address

Vali Asr hospital, Shahid Shiroudi Street, Arak, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr. Alireza Kamali

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Arak 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

Arak University of Medical Sciences

Full name of responsible person

Dr Sedigheh Darvish Shafiqi

Position

Arak

Latest degree

Specialist

Other areas of specialty/work

General Surgery

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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

Dr Fatemeh Safi

Position

Associate professor

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Other areas of specialty/work

Radiology

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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

Yes - There is a plan to make this available

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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

After conducting this study and analytical studies on it, only a part of the data such as information about the main outcome and patient demographic information will be published to the researchers who do the necessary correspondence with the person in charge of this study.

When the data will become available and for how long

Access will be from 2023/4/20 to 2026/4/20 for 3 years.

To whom data/document is available

University researchers

Under which criteria data/document could be used

Academic researchers or university professors or students who intend to use the data of this study, after obtaining permission from the relevant people mentioned, can use the information of this study in the field of metallurgical studies or other relevant review studies. In addition, if requested, they can use the information of this study for the prerequisites of their future studies and the existence of questions and ambiguities. Using the information of this study is subject to mentioning the names and logos of the responsible persons in this study.

From where data/document is obtainable

University researchers and university professors, after contacting the relevant professor by text message or e-mail, can request the use of data from Dr. Safi and then Dr. Bashiri, respectively. Dr. Fatemeh Safi: Address: Valiasr Hospital, Shahid Shiroodi St., Arak Postal Code: 3814957558 Phone: 09183617577 Email: safiarak95@gmail.com Dr. Soodabeh Bashiri Address: Valiasr Hospital, Shahid Shiroodi St., Arak Postal Code: 3814957558 Phone: 09181413783 Email: dr.bashiri1985@gmail.com

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

Letter writing should be done with professors and

universities.

Comments