Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

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Amin Haji seyyed hoseini

Name of organization / entity

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Iran (Islamic Republic of)

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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
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Sponsors / Funding sources

1

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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
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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