Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of changes in sera levels of interleukin 1 β (IL-1β), IL-6, IL-8, and anti-mullerian hormone (AMH) following ethanol sclerotherapy in patients with endometrioma using reterntion method

Protocol summary

Study aim

Evaluation of changes in sera levels of interleukin 1 β (IL-1β), IL-6, IL-8, and anti-mullerian hormone (AMH) following ethanol sclerotherapy in patients with endometrioma using reterntion method

Design

This study is a clinical trial with 25 patients with endometriosis without control group and one-way blind.

Settings and conduct

This study will be performed on 25 patients with endometriosis who have been referred to Al-Zahra Hospital in Tabriz.In this study, only the data analyzer will be blind.The type of sampling method will be non-random.Before any intervention, the sera levels of interleukin (IL) 1 β, IL-6, IL-8, and antimullerian hormone would be evaluated. Then, using transvaginal ultrasound evaluation the cyst will be detected and the filling fluid aspirated and washed until it became clear. After that, about 75% of the apirated volume would be injected into the cyst and the patient will be discharged after recommendations.

Participants/Inclusion and exclusion criteria

In this study, patients with endometriosis will be included in the study and in case of inflammatory and autoimmune diseases as well as patients with cysts with a volume of more than 150 ml will be barred from entering the study.

Intervention groups

Using transvaginal ultrasound evaluation the cyst will be detected and the filling fluid aspirated and washed until it became clear. After that, about 75% of the apirated volume would be injected into the cyst and the patient will be discharged after recommendations.

Main outcome variables

IL-1β level assessment; IL-6; IL-8; AMH and cyst recurrence are the consequences of this study.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130115012146N9**
Registration date: **2021-11-06, 1400/08/15**
Registration timing: **registered_while_recruiting**

Last update: **2021-11-06, 1400/08/15**
Update count: **0**

Registration date

2021-11-06, 1400/08/15

Registrant information

Name

Laaya Farzadi

Name of organization / entity

Woman's Reproductive Health Research Center of Tabriz

Country

Iran (Islamic Republic of)

Phone

+98 41 1553 9161

Email address

farzadl@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-03, 1400/08/12

Expected recruitment end date

2022-11-03, 1401/08/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation of changes in sera levels of interleukin 1 β (IL-1β), IL-6, IL-8, and anti-mullerian hormone (AMH) following ethanol sclerotherapy in patients with endometrioma using reterntion method

Public title
Evaluation of serum changes in inflammatory agents in patients with endometrioma after ethanol injection by residual method

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Women with symptomatic endometrial cysts above 3 cm Women with asymptomatic endometrial cysts above 3 cm Willingness to cooperate
Exclusion criteria:
Patients with a history of malignancy Patients with a history of inflammatory and autoimmune diseases Patients with a history of corticosteroid and immunosuppressive drugs Patients with a history of taking non-steroidal anti-inflammatory drugs for the past 7 days Patients with abnormal CEA-125 levels Patients with cysts with a volume of more than 150 ml

Age
No age limit

Gender
Female

Phase
2

Groups that have been masked

- Data analyser

Sample size
Target sample size: **25**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description
supervisor ،who is not involved in the collection and analysis of study data and the researcher will be aware of the study groups and the data analyst will be blinded

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Tabriz University of Medical Sciences
Street address
Golgasht Street ,Tabriz University Of Medical Sciences
City
Tabriz
Province
East Azarbaijan
Postal code
5166616471

Approval date
2021-10-04, 1400/07/12

Ethics committee reference number
IR.TBZMED.REC.1400.598

Health conditions studied

1

Description of health condition studied
Endometriosis of ovary

ICD-10 code
N80.1

ICD-10 code description
Endometriosis of ovary

Primary outcomes

1

Description
Evaluation of serum interleukin (IL) levels 1β

Timepoint
Before the intervention and three months after the end of the intervention

Method of measurement
Blood test

2

Description
Evaluation of serum IL-6 levels

Timepoint
Before the intervention and three months after the end of the intervention

Method of measurement
Blood test

3

Description
Evaluation of serum IL-8 levels

Timepoint
Before the intervention and three months after the end of the intervention

Method of measurement
Blood test

4

Description
Evaluation of serum AMH levels
Timepoint
Before the intervention and three months after the end of the intervention
Method of measurement
Blood test

Secondary outcomes

1

Description
Recurrence of the cyst
Timepoint
Before the intervention and three months after the end of the intervention
Method of measurement
Vaginal ultrasound

Intervention groups

1

Description
Before any intervention, the sera levels of interleukin (IL) 1 β, IL-6, IL-8, and antimullerian hormone would be evaluated. Then, using trans vaginal ultrasound evaluation the cyst will be detected and the filling fluid aspirated and washed until it became clear. After that, about 75% of the apirated volume would be injected into the cyst and the patient will be discharged after recommendations. up:
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra Hospital
Full name of responsible person
Dr.Farzadi Laya
Street address
Alzahra Hospital, South Artesh Ave
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5138663134
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lahroudin@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Dr.Mohammad Samiei
Street address
No. 2 Central Building, Tabriz University of Medical Sciences, Golgasht Street
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Email
research-vice@tbzmed.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
Dr.Farzadi Laaya
Position
Fellowship of Infertility
Latest degree
Subspecialist
Other areas of specialty/work
Gynecology and Obstetrics
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available