

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of changes in sera levels of interleukin 1 β (IL-1 β), 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-1 β), 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-1 β 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-1 β), 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 1 β

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 aspirated 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

City

Tabriz

Province

East Azarbaijan

Postal code

5138663134

Phone

+98 41 3553 9161

Email

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

City

Tabriz

Province

East Azarbaijan

Postal code

5138665793

Phone

+98 41 3335 7310

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

Street address

Golgasht Street, Tabriz University Of Medical Sciences

City

Tabriz

Province

East Azarbaijan

Postal code

5166616471

Phone
+98 41 3553 9161
Email
lahroudin@gmail.com

Person responsible for scientific 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
Street address
Golgasht Street, Tabriz University Of Medical Sciences
City
Tabriz
Province
East Azarbaijan
Postal code
5166616471
Phone
+98 41 3553 9161
Email
lahroudin@gmail.com

Person responsible for updating data

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
Street address
Tabriz University Of Medical Sciences, Golgasht Street
City
Tabriz
Province
East Azarbaijan
Postal code
5138665793
Phone
0098 35519161
Email
lahroudin@gmail.com

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