

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Efficacy of aspiration and Ethanol sclerotherapy in primary and recurrent endometrioma on IVF outcome

#### Protocol summary

##### Study aim

comparison of the IVF outcome following ovarian aspiration and sclerotherapy and cases without this protocol in primary and recurrent endometrioma.

##### Design

two arm parallel group blinded randomised clinical trial with 40 patient in control and 40 in the intervention group.

##### Settings and conduct

AFC and size of their endometrioma and AMH, FSH, Estradiol and CA125 is measured. patients are randomly divided into two control and intervention groups. in intervention group of infertile patients of Shariati hospital with history of primary or recurrent endometriosis, cyst content is aspirated and substituted by 98% ethanol and then reaspirated. patients are discharged with ampule of Diphereline. if patients are free from cyst and their endometrial thickness(ET) is less than 4mm, ovulation induction is started. In control group also, Diphereline is prescribed. after the dose if their ET is less than 4mm, ovulation induction is started. 2 weeks after embryo transfer, serum B-hcG in both groups are measured and if it is positive, TVS is ordered in 3 weeks time and in case of observation of fetal heart rate, this is considered a positive clinical pregnancy.

##### Participants/Inclusion and exclusion criteria

infertile, 20 to 40 years old female with endometrioma with exclusion criteria of: liver, kidney or heart diseases. endometrioma larger than 10 centimeter(cm) or smaller than 3cm with a thickened wall and suspicious for malignancy.

##### Intervention groups

after sclerotherapy, ampule of Diphereline is prescribed. if patients are free from ovarian cyst and their endometrial thickness(ET) is less than 4mm, ovulation induction is started. In control group also, after last dose if their ET is less than 4mm, ovulation induction is started.

##### Main outcome variables

Fertility rate Pregnancy Rate

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20191206045629N1**

Registration date: **2020-05-06, 1399/02/17**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-05-06, 1399/02/17**

Update count: **0**

##### Registration date

2020-05-06, 1399/02/17

##### Registrant information

##### Name

leila shahsavari

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2206 8580

##### Email address

shahsavari\_l@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-04-18, 1399/01/30

##### Expected recruitment end date

2020-07-20, 1399/04/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

Efficacy of aspiration and Ethanol sclerotherapy in primary and recurrent endometrioma on IVF outcome

### Public title

Efficacy of aspiration and Ethanol sclerotherapy in primary and recurrent endometrioma on IVF outcome

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

all infertile women in shariati hospital, in 20-40 year age interval with primary or recurrent endometrioma

#### Exclusion criteria:

having or history of hepatic having or history of renal having or history of cardiac diseases having or history of any endometrioma larger than 10 cm and smaller than 3 cm having or history of any cyst with thickened wall suspicious for malignancy

### Age

From **20 years** old to **40 years** old

### Gender

Female

### Phase

N/A

### Groups that have been masked

- Participant

### Sample size

Target sample size: **80**

### Randomization (investigator's opinion)

Not randomized

### Randomization description

### Blinding (investigator's opinion)

Single blinded

### Blinding description

Patients will be informed of the possibility of a new intervention to increase the likelihood of fertility, but no information will be given on which of the patients will be given this operation. Due to the fact that therapists were unaware of the possible intervention, blinding was performed. Double-blinding was not feasible in this study.

### Placebo

Not used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

ethics committee of tehran university of medical

sciences

### Street address

Tehran-saadat abad- bulvard 24 meter- dasht behesh- between 4th and 5th west street#6 frist floor

### City

Tehran

### Province

Tehran

### Postal code

1998683611

### Approval date

2019-04-16, 1398/01/27

### Ethics committee reference number

IR.TUMS.MEDICINE.REC.1398.019

## Health conditions studied

### 1

#### Description of health condition studied

Ovarian endometrioma

#### ICD-10 code

N80.1

#### ICD-10 code description

Endometriosis of ovary

## Primary outcomes

### 1

#### Description

Fertility rate/ Pregnancy Rate

#### Timepoint

at the end of study

#### Method of measurement

observation of fetal heart activity by ultrasound

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: 2 to 3 days after the termination of menstruation, in the operating room under conscious sedation and in the lithotomy position, under the ultrasound guidance, ovarian cyst content is aspirated. afterward, 80% of the aspirated volume of cyst is substituted by 98% ethanol for 15 minutes and then aspirated.

#### Category

Treatment - Surgery

### 2

#### Description

Control group: Intervention group: 2 to 3 days after the termination of menstruation, in the operating room under conscious sedation and in the lithotomy position, under

the ultrasound guidance, ovarian cyst content is aspirated. afterward, 80% of the aspirated volume of cyst is substituted by Normal saline for 15 minutes and then aspirated.

**Category**

Treatment - Surgery

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Shariati hospital

**Full name of responsible person**

Ashraf aleyasin

**Street address**

north kargar street, jalal al ahmad avenue

**City**

Tehran

**Province**

Tehran

**Postal code**

1411713135

**Phone**

+98 21 8490 1000

**Fax**

+98 21 8863 3039

**Email**

shariatihospital@tums.ac.ir

**Web page address****Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Dr. Sahraeian

**Street address**

north kargar street, jalal alahmad avenue, shariati hospital

**City**

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**Province**

Tehran

**Postal code**

1411713135

**Phone**

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**Email**

alyasina@tums.ac.ir

**Web page address****Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Tehran 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**

Tehran University of Medical Sciences

**Full name of responsible person**

Leila shahsavari

**Position**

obstetrics and gynecology resident

**Latest degree**

Specialist

**Other areas of specialty/work**

Gynecology and Obstetrics

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shahsavari\_l@yahoo.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

ashraf aleyasin

**Position**

professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Gynecology and Obstetrics

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**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

leila shahsavari

**Position**

resident

**Latest degree**

Specialist

**Other areas of specialty/work**

Gynecology and Obstetrics

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**Email**

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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