

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

Tehran

Province

Tehran

Postal code

1411713135

Phone

+98 21 8490 1000

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

Street address

saadat abad, bulvard 24 meter, dashte behesh, between 4th and 5th street#6 first floor

City

Tehran

Province

Tehran

Postal code

1998683611

Phone

+98 21 2206 8580

Email

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

Street address

north kargar street, jalal al ahmad avenue, shariati hospital

City

tehran

Province

Tehran

Postal code

1411713135

Phone

+98 21 8490 1000

Email

alyasina@tums.ac.ir

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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saadat abad.24 meter boulevard. dashte behesht
between 4rth and 5th west street #6 first flor

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Province

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Postal code

1998683611

Phone

+98 21 2206 8580

Email

shahsavari_l@yahoo.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