Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 2026

The comparison of the efficacy of ethanol injection with no ethanol injection on pregnancy outcome in IVF cycles among patients with recurrent endometrioma

Protocol summary

Study aim
The aim of this trial is to compare the IVF outcome among the women with recurrent endometrioma with and without ethanol injection

Design
This clinical trial with control group and two parallel arms without blindness, phase 2 using randomization by random number table was performed on 40 patients with recurrent endometrioma.

Settings and conduct
The location where the study is conducted is Yazd Research and Clinical Center for Infertility affiliated to Yazd Shahid Sadoughi University of Medical Sciences, Yazd.

Participants/Inclusion and exclusion criteria
Inclusion criteria: being at the age of 20 to 39 years; Past history of operation on endometrioma with recurrent unilateral endometrioma; Recurrent endometrioma cyst with a size of more than 30 mm; FSH<10. Exclusin criteria:liver or kidney or heart diseases; sever male factor infertility

Intervention groups
Intervention group: 20 patients with recurrent endometrioma go through sclerotherapy under vaginal sonography guidance .The needle is introduced into endometrioma and aspiration is done under sonographic guidance. The endometrioma is irrigated with sterile normal saline till the fluid is clear in color. The endometrioma is filled with 98% ethanol for 10 minute and at the end ethanol is aspirated. Then the patients were followed up after one week, one, two, and three months. At this time If the patients have no any endometrioma they are treated with IVF long protocol. Control group: 20 patients with recurrent endometrioma go through IVF long protocol who do not treated by ethanol sclerotherapy.

Main outcome variables
Recurrence of endometrioma

General information

Reason for update
Updating the trial according to the last changes in inclusion and exclusion criteria, actual number of cases, date of recruitment and trial completion and adding the trial result

Acronym

IRCT registration information
IRCT registration number: **IRCT201108024339N4**
Registration date: **2011-08-15, 1390/05/24**
Registration timing: **registered_while_recruiting**

Last update: **2021-04-13, 1400/01/24**
Update count: **1**

Registration date
2011-08-15, 1390/05/24

Registrant information

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Recruitment status
Recruitment complete

Funding source
Yazd research and clinical center for infertility

Expected recruitment start date
2011-03-01, 1389/12/10

Expected recruitment end date
2011-09-01, 1390/06/10
Actual recruitment start date
2011-03-01, 1389/12/10
Actual recruitment end date
2011-09-01, 1390/06/10
Trial completion date
2012-02-29, 1390/12/10

Scientific title
The comparison of the efficacy of ethanol injection with no ethanol injection on pregnancy outcome in IVF cycles among patients with recurrent endometrioma

Public title
The efficacy of alcohol injection in endometrioma
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Being at the age of 20 to 39 years Past history of operation on endometrioma with recurrent unilateral endometrioma Recurrent endometrioma more than 30 mm FSH<10
Exclusion criteria:
liver or kidney or heart diseases sever male factor infertility
Age
From **20 years** old to **39 years** old
Gender
Female

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **40**
Actual sample size reached: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Women with recurrent endometrioma who met the inclusion criteria were were informed about the research design and signed a written consent form for randomly assignment into either case or control groups. Randomization was simple, individual using a random number table. All women were consecutively divided into two groups based on the randomized list.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Yazd research and clinical center for infertility
Street address
Yazd research and clinical center for infertility, Booali Street, Safaieh, Yazd
City
Yazd
Province
Yazd
Postal code
8916877391
Approval date
2011-06-20, 1390/03/30
Ethics committee reference number
938

Health conditions studied

1

Description of health condition studied
endometriosis
ICD-10 code
N80.1
ICD-10 code description
اندومتریوز تخمدان

Primary outcomes

1

Description
The size of endometrioma
Timepoint
One week ; one, two, three and six months after surgery
Method of measurement
sonography

Secondary outcomes

1

Description
Chemical pregnancy
Timepoint
14 days after embryo transfer
Method of measurement
serum BHCG

2

Description
Fertilization rates
Timepoint
Three days after fertilization
Method of measurement

The total number of embryos created is divided by the number of second metaphase oocytes multiplied by 100

3

Description
Implantation rates
Timepoint
Five weeks after transfer
Method of measurement
The number of gestational sacs divided by the number of transferred embryos multiplied by 100

4

Description
Clinical pregnancy rate
Timepoint
7 weeks after embryo transfer
Method of measurement
Fetal heart rate in ultra sonography

Intervention groups

1

Description
Intervention group: 20 patients with recurrent endometrioma go through sclerotherapy under vaginal sonography guidance . The needle is introduced into endometrioma and aspiration is done under sonographic guidance. The endometrioma is irrigated with sterile normal saline till the fluid is clear in color. The endometrioma is filled with 98% ethanol for 10 minute and at the end ethanol is aspirated. Then the patients were followed up after one week, one, two, and three months. At this time If the patients have no any endometrioma they are treated with IVF long protocol.
Category
Treatment - Drugs

2

Description
Control group: 20 patients with recurrent endometrioma go through IVF long protocol who do not treated by ethanol sclerotherapy.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Yazd research and clinical center for infertility
Full name of responsible person
Abbas Aflatoonian
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Yazd research and clinical center for infertility, Booali Street, Safaieh, Yazd
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yazd University of Medical Sciences
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Vice-Chancellor for Research & Technology
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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
Yazd 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
Yazd University of Medical Sciences
Full name of responsible person

Abbas Aflatoonian

Position
Obestetrics and Gynecologist, fellowship

Latest degree
Specialist

Other areas of specialty/work
Gynecology and Obstetrics

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Latest degree
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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
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is 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
Yes - There is 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

Title and more details about the data/document
Information on the main outcome

When the data will become available and for how long
6 months after printing the results

To whom data/document is available
Editor-in-Chief

Under which criteria data/document could be used
use in the retrospective study

From where data/document is obtainable
Yazd research and clinical center for infertility

What processes are involved for a request to access data/document
Request from the Research Deputy, submitted to the Research Council of the Center if the request accepts its referral to the security and after completion of the relevant forms, request is referred to the research experts and then get the data.

Comments

Trial results

Please tick if results have been published

Yes

Summary result posting date

2021-04-13, 1400/01/24

Table of baseline comparison

Table I

Baseline patient characteristics

	Study group Mean ± SD	Control group Mean ± SD	p-value
Age (years)	29.4 ± 5.76	31 ± 3.89	0.231
Duration of infertility (years)	5.05 ± 2.85	6.5 ± 2.81	0.072
FSH (IU/ml)	6.97 ± 2.25	6.64 ± 2.44	0.565
LH (IU/ml)	5.83 ± 2.18	6.03 ± 2.07	0.862
TSH (mIU/L)	2.53 ± 0.8	2.14 ± 0.64	0.149
Antral follicular count(number)	8.8 ± 1.6	8.25 ± 2.1	0.369

Mann-Witney and t-test, p-value <0.05 significant

Participant flow diagram

Allocated to intervention (n= 20)

- Received allocated intervention without ethanol sclerotherapy (n= 20)
- Did not receive allocated intervention (give reasons) (n= 0)

Assessed for eligibility (n= 40)

Lost to follow-up (give reasons) (n= 0)

- Discontinued intervention (give reasons) (n= 0)

Analysed (n= 20)

- Excluded from analysis (give reasons) (n= 0)

Excluded (n=0)

- Not meeting inclusion criteria (n=0)
- Declined to participate (n=0)
- Other reasons (n=0)

Analysed (n=20)

Excluded from analysis (give reasons) (n= 0)

Lost to follow-up (give reasons) (n= 0)

- Discontinued intervention (give reasons) (n= 0)

Allocated to intervention (n= 20)

- Received allocated intervention with ethanol sclerotherapy (n=20)
- Did not receive allocated intervention (give reasons) (n= 0)

Randomized (n=40)

CONSORT 2010 Flow Diagram

Table of variable outcomes' results

Comparison of IVF outcomes in both groups

	Mean ± SD Study group	Mean ± SD Control group	p-value
Total dose of gonadotropin (IU)	2491.6 ± 662.6	2523.7 ± 499.4	0.866
Estradiol (On the Day of HCG)	1466.6 ± 1367.6	1280 ± 892.8	0.874
Duration of gonadotropin	8.94 ± 1.21	9.65 ± 2.25	0.553
NO. of Follicle	10.5 ± 3.88	9.4 ± 3.39	0.331
NO. of total oocyte	7.83 ± 2.22	7.55 ± 4.77	0.393
NO. of total embryo	4.72 ± 2.76	3.8 ± 2.56	0.319
NO. of embryo transfer	2.17 ± 0.7	2.35 ± 0.67	0.331
NO. of Metaphase II oocyte	6.11 ± 2.34	5.45 ± 3.18	0.476

NO= Number, Mann-Witney and t-test, p-value <0.05 significant, HCG=Human Chorionic Gonadotropin

Comparison of pregnancy results in both groups

	Study group No (%)	Control group No (%)	p-value
Chemical pregnancy	6 (33.3%)	4 (20%)	0.468
Clinical pregnancy	5 (27.8%)	3 (15%)	0.616
Fertilization rate	63.06%	60.38%	0.57
BMI (kg/m^2)	25.00±3.2	24.30±3.6	0.557

NO=Number, Mann-Witney and t-test, p-value <0.05 significant

Table of adverse events

no

First publication date

2013-03-29, 1392/01/09

Abstract of published paper

Background: Endometriosis is a common hormone-dependent gynecologic disease with a high recurrence. Laparotomy or laparoscopy is the standard surgery for the large endometrioma. Also, sclerotherapy is basically used to treat different diseases one of which is endometrioma. Objective: The study was designed to assess the value of transvaginal ultrasound-guided ethanol sclerotherapy in patients with a recurrent endometrioma. Materials and Methods:In a randomized clinical trial, an interventional group of 20 patients underwent transvaginal ethanol sclerotherapy for recurrent ovarian endometrioma. The patients were followed up first after one and two weeks and then after one, two, and three months. If the patients had no endometrioma, they were treated with in vitro fertilization (IVF) (standard long protocol). A control group of 20 patients with endometrioma were enrolled for an IVF protocol. They had no treatment by ethanol sclerotherapy. IVF parameters, pregnancy rates, and implantation rates were compared in both groups. Results: The demographic data showed no difference between the two groups. The initial mean endometria size was 41.45±15.9

cm, the recurrence rate after 6 months was 4 (20%), FSH before and after sclerotherapy was 6.97±2.25 IU/L and 6.78±1.88 IU/L (p=0.343). The clinical pregnancy rate was 6 (33.3%) vs. 3 (15%), (p=0.616). The fertilization rate emerged 63.06% in study group vs. 60.38%, (p=0.57). The implantation rate turned out 12.9% in study group vs. 7.5%, (p=0.52). None of these results were significant. However, the data pointed to a better trend toward the ethanol sclerotherapy group. Conclusion:Ethanol sclerotherapy could be an effective strategy for the treatment of recurrent endometrioma especially before IVF.