

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of suppressive hormonal therapy(LD tablet) with aspiration in regression of ovarian endometrioma

Protocol summary

Summary

The aim of this study is comparison of hormone suppressor (LD pill) with aspiration in regression of ovarian endometrioma. In this study womens aged 15-45 who have reffered to Al-Zahra Hospital with ultrasonographic criteria that who have had unilateral endometrioma with size less than or equal to 6 centimeters and test CA 100> 125, randomly placed in one of the following groups. The possibility of malignancy will be excluded. A) Hormone Suppressor Group: after taking informed consent, patinets daily received one LD pill for three months and at the end, the ultrasound is performed again in terms of cyst regression. Up to 3 months after treatment and cyst regression, the patients will be followed. Questionnaire at the time of inclusion, one, three and six months after treatment, the improvement of clinical symptoms (including: dysmenorrhea, dyspareunia and pelvic pain), regression or recurrence of cyst will be filled. B) Aspiration Group: after taking informed consent, cyst aspiration under the ultrasound is done by one of the associates of infertility. Three and six months after aspiration, ultrasound is performed again in terms of the re-formation of cysts. Questionnaire at the time of inclusion, one, three and six months after aspiration, in terms of clinical improvement and cyst recurrence and need to re-aspiration will be filled. After determining inclusion criteria, division of patients will be done with block randomization and the corresponding software. The study is not blinded. primary outcome: cyst regression, improvement of clinical symptoms, including: dysmenorrhea, dyspareunia and pelvic pain.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201609105563N8**

Registration date: **2016-10-02, 1395/07/11**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-10-02, 1395/07/11

Registrant information

Name

Elaheh Ouladsahebmadarek

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1554 1221

Email address

madarek@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor For Research, Tabriz University Of Medical Sciences

Expected recruitment start date

2016-10-01, 1395/07/10

Expected recruitment end date

2019-08-01, 1398/05/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of suppressive hormonal therapy(LD tablet) with aspiration in regression of ovarian endometrioma

Public title

Comparison of suppressive hormonal therapy(LD tablet) with aspiration in regression of ovarian endometrioma

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: womens aged 15-45; unilateral endometrioma, endometrioma diagnosis with ultrasound; CA 125<100; mass size less than or equal to 6 cm
Exclusion criteria: the possibility of malignancy; contraindications of LD pill; ischemic heart disease or previous history of it; current breast cancer; liver tumors (benign and malignant))

Age

From **15 years** old to **45 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee Of Tabriz University Of Medical Sciences.

Street address

Third Floor, Central Building of Number2, Golgasht Street

City

Tabriz

Postal code

Approval date

2016-09-06, 1395/06/16

Ethics committee reference number

IR.TBZMED.REC.1395.572

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

size of the cyst

Timepoint

One, three and six months after treatment

Method of measurement

Questionnaire

Secondary outcomes

1

Description

Dysmenorrhea

Timepoint

One, three and six months after treatment

Method of measurement

Questionnaire

2

Description

Dyspareunia

Timepoint

One, three and six months after treatment

Method of measurement

Questionnaire

3

Description

Pelvic pain

Timepoint

One, three and six months after treatment

Method of measurement

(Incontinence quality of life =I-QOL)

Intervention groups

1

Description

In intervention group A: LD tablets daily for three months a number

Category

Treatment - Drugs

2

Description

The intervention group B: Aspiration of the cyst

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Hospital

Full name of responsible person

Elaheh Ouladsahebmadarek

Street address

Alzahra Hospital, South Artesh St.,Tabriz, iran

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for Research,Tabriz University Of Medical Sciences

Full name of responsible person

Dr.Alireza Rashidi

Street address

Third Floor, Central Building of Number2, Golgasht Street

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Tabriz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for Research,Tabriz University Of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Tabriz University Of Medical Sciences

Full name of responsible person

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Position

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty