

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

Comparison of the Therapeutic effect of Oral Contraceptives with and without Dopamine Agonist (Cabergoline) in Reducing the Size of Ovarian Benign Tumors

Protocol summary

Study aim

This study will be done with the aim of assessing the therapeutic effect of administration of Oral Contraceptives with or without Dopamine Agonist (Cabergoline), in reducing the size of benign ovarian tumors.

Design

A randomised, single centered, triple blinded clinical trial with parallel intervention and control groups; consisting of 40 participants.

Settings and conduct

The setting is Tabriz Alzahra Hospital. Participants, using a single randomization procedure, will be divided into two groups. Group 1 will receive Oral Contraceptives and group 2 will receive Cabergoline and Oral Contraceptives for 3 months. At the end of this time the size of benign ovarian tumors in two groups will be compared. The study is triple blinded meaning that the researcher, participants and analyst will not be aware of the division of the two groups.

Participants/Inclusion and exclusion criteria

Participants in this study will be all women with benign ovarian tumors in reproductive age. Inclusion criteria: All women with benign ovarian tumors in reproductive age. Non inclusion criteria: hyperprolactinemia; hypercoagulability state and valvular heart disease.

Intervention groups

Control group will receive Oral Contraceptives, and Intervention group will receive Oral Contraceptives and Cabergoline(dopamine agonist).

Main outcome variables

The size of benign ovarian tumors

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180815040802N1**

Registration date: **2018-08-27, 1397/06/05**

Registration timing: **registered_while_recruiting**

Last update: **2018-08-27, 1397/06/05**

Update count: **0**

Registration date

2018-08-27, 1397/06/05

Registrant information

Name

Marzieh Parizad nasirkandi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3553 9161

Email address

parizadm@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-06, 1397/05/15

Expected recruitment end date

2018-11-06, 1397/08/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Therapeutic effect of Oral Contraceptives with and without Dopamine Agonist (

Cabergoline) in Reducing the Size of Ovarian Benign Tumors

Public title
Therapeutic Effect of Dopamine Agonist (Dopamine) in Comparison with Oral Contraceptives in Reducing the Size of Ovarian Benign Tumors

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
All women with Benign Ovarian Tumors in Reproductive Age
Exclusion criteria:
Hyperprolactinemia Hypercoagulability State Valvular Heart Disease

Age
From **15 years** old to **49 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
The Participants, will be divided into 2 groups with a single randomization procedure(computer generated random numbers). Each group consists of 20 participants.Group 1 will receive Oral Contraceptives and group 2 will receive Cabergoline and Oral Contraceptives.

Blinding (investigator's opinion)
Triple blinded

Blinding description
The study is triple blinded meaning that the researcher, participants, and analyst will not be Aware of the Division of 2 Groups.

Placebo
Not 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
Tabriz University of Medical Sciences, Attar Neyshabouri Street, Tabriz, Iran
City
Tabriz
Province
East Azarbaijan
Postal code
5138663134
Approval date
2018-08-06, 1397/05/15
Ethics committee reference number
IR.TBZMED.REC.1397.411

Health conditions studied

1

Description of health condition studied

Benign Ovarian Tumors

ICD-10 code

D27

ICD-10 code description

D27:Benign neoplasm of ovary

Primary outcomes

1

Description

Size of benign ovarian tumor

Timepoint

measuring the size of tumor before intervention and after the 3 months; receiving drug

Method of measurement

Trans Vaginal Ultrasound

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: participants will receive 25 milligram Cabergoline (dopamine agonist) tablets orally twice a week and Oral Contraceptives daily for 3 months.

Category

Treatment - Drugs

2

Description

Control group: Participants will receive only Oral Contraceptives daily for 21 days monthly, then continue after the interval of about 8 days with next month; using for 3 months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Tabriz Alzahra Hospital

Full name of responsible person

Marzieh Parizad Nasirkandi

Street address

Alzahra Hospital, Baghshomal Crossroad, South
Artesh Ave, Azadi Blvd, Baghshomal Town, Tabriz

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parizadm@tbzmed.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Office of the Vice Chancellor for Research of Tabriz
University of Medical Sciences

Street address

Tabriz University of Medical Sciences, Attar
Neyshabouri Street, Tabriz, Iran

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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

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

Kosar Aghajani

Position

Medical Student

Latest degree

A Level or less

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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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

No - There is not 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

No - There is not 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