

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jul 2026

### Ovulation induction with clomiphene citrate and letrozole versus letrozole and cabergoline in fertility rate and its complications in infertile polycystic ovary syndrome women referred to gynecologic clinic

#### Protocol summary

##### Study aim

Comparing the effect of clomiphene + letrozole with letrozole + cabergoline to induce ovulation and pregnancy outcomes

##### Design

Clinical trial ; Simple randomization; Sample size of 60 patients in two groups of 30 people; triple blind

##### Settings and conduct

Patients referred to Jahrom Women's Clinic will be placed in two groups A and B by easy sampling and random allocation. Blinding will be done in three ways, at the sample level, the Assistant researcher and the researcher. Group A receives clomiphene and letrozole tablets and group B receives letrozole and cabergoline tablets. Follow-up response to treatment with vaginal ultrasound (Samsung HS60) on days 8 and 12 after examining the condition of the follicles, each patient from the two studied groups who has an adult follicle, HCG ampoule is injected to release the follicle. Pregnancy will be diagnosed by ultrasound (by Dr. Talebnia) and  $\beta$ -HCG titer test (in Dr. Zare's laboratory by ECL method by E411 device)

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Infertile women aged 15-45 years with polycystic ovary syndrome who have not had a history of pregnancy after 12 months of unprotected intercourse, Normal hysterosalpingography  
Exclusion criteria: Uterine and adnexal pathology, Thyroid and prolactin disorders, FSH above 9

##### Intervention groups

Group A receives two clomiphene 50 mg tablets daily from the 3th to the 7th day of menstruation, and then two 2.5 mg letrozole tablets from the 8th to the 11th day of menstruation. Group B receives two 2.5 mg letrozole tablets daily from the 3th to the 11th day, and then receives two 0.5 mg cabergoline tablets daily from the 8th day until the 11th day. In both groups, ultrasound will

be performed on days 8 and 12 of the menstrual cycle to assess the number and size of follicles and the endometrial thickness

##### Main outcome variables

Ovulation ; Pregnancy

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200122046221N2**

Registration date: **2020-08-21, 1399/05/31**

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

Last update: **2020-08-21, 1399/05/31**

Update count: **0**

##### Registration date

2020-08-21, 1399/05/31

##### Registrant information

##### Name

athar rasekhjahromi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 5426 6602

##### Email address

drasekh@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-08-05, 1399/05/15

##### Expected recruitment end date

2021-02-03, 1399/11/15

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Ovulation induction with clomiphene citrate and letrozole versus letrozole and cabergoline in fertility rate and its complications in infertile polycystic ovary syndrome women referred to gynecologic clinic

**Public title**

Induction of ovulation in women with ovarian laziness

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Infertile women with polycystic ovary syndrome who have not had a history of pregnancy without contraception after 12 months Women with no ovulation Normal hysterosalpingography with open fallopian tubes Diagnosis of infertility by non-ovulation, which is diagnosed according to standard criteria Written conscious desire and satisfaction Infertility at the age of 15-45 years

**Exclusion criteria:**

Uterine and adnexal pathology such as leiomyoma, endometriosis, etc. Hyperprolactinemia/Hyperthyroidism or hypothyroidism Liver or kidney dysfunction Diabetes mellitus or random blood sugar above 140 mg / dL Previous genital surgery Appendicitis, peritonitis, genital tuberculosis in history or having abnormal pelvic anatomy FSH above 9 in the early stage of the follicular phase

**Age**

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

**Gender**

Female

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In the present study, a simple randomization method will be used, which based on the list of samples and their numbering using a table of random numbers (using Random Allocation Software 1.0) that people are divided into two groups. The first group will induce ovulation with clomiphene citrate and letrozole and the second group will induce ovulation with letrozole and cabergoline. -

Randomization method and description of each method:

Simple randomization -Randomization unit: individual -

Randomization layers: In this study, there is no simple layer due to the type of random allocation. -

Randomization tool: Random number table (using

Random Allocation Software 1.0). -How to make a

random sequence: According to the use of software and

the definition of two groups and the number of sample

sizes required in each, the group for the software

numbers are randomly assigned in two groups, it is

obvious that each number represents one of the sample.

-Explanation about allocation concealment: Concealment

was done centrally by the Statistics Counseling Center of

Jahrom University of Medical Sciences and by one of the

statistical consultants so that the researcher does not

interfere in assigning samples to groups.

**Blinding (investigator's opinion)**

Triple blinded

**Blinding description**

While obtaining written consent from patients to

participate in the study They only knew that they were

studying to find the best way to induce ovulation, but

they did not know which group of drugs was included in

the drug coding, in order to observe ethics in the

research, the structure of the study was explained to

them and after their agreement, the samples were

included in the study (Single blind).the ampoules and

tablets were presented to the researchers in similar

syringes and covers respectively (with special codes ) so

that it could not be identified for the assistant

researchers (the nurse of Jahrom Women's Clinic).

Accordingly, the assistant researchers participated in

prescribing the drug to patients, although they knew

what the drug's content was in each package, were

unaware of the research hypotheses. It should be noted

that the participants in each group were unaware of the

drug regime of the opposite group.(Double blind).

Because the researcher(the gynecologist and professor

of Jahrom University of Medical Sciences) did not know

about the coding system but the assistant researchers

knew about this system. Therefore, until the end of the

analysis and before the generalization of the

calculations, the researcher did not know which group

the collected data belonged to. Obviously, the assistant

researchers wrote down the data belonging to the groups

somewhere and gave it to the researcher after analyzing

the data (Triple blind).

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees**

1

**Ethics committee**

### Name of ethics committee

Ethics Committee of Jahrom University of Medical Sciences

### Street address

Jahrom-Ostad Motahari Street-After School of Nursing- Jahrom University of Medical Sciences-Pardis site.

### City

Jahrom

### Province

Fars

### Postal code

۷۴۱۴۸-۴۶۱۹۹

### Approval date

2020-07-12, 1399/04/22

### Ethics committee reference number

IR.JUMS.REC.1399.051

## Health conditions studied

### 1

#### Description of health condition studied

Polycystic Ovary Syndrome(PCO)

#### ICD-10 code

E28.2

#### ICD-10 code description

Polycystic ovarian syndrome

## Primary outcomes

### 1

#### Description

The size of the grown follicles

#### Timepoint

Days 8 and 12 of the menstrual cycle

#### Method of measurement

Transvaginal ultrasound

## Secondary outcomes

### 1

#### Description

Number of grown follicles

#### Timepoint

Days 8 and 12 of the menstrual cycle

#### Method of measurement

Transvaginal ultrasound

### 2

#### Description

Endometrial thickness

#### Timepoint

Days 8 and 12 of the menstrual cycle

#### Method of measurement

Transvaginal ultrasound

## Intervention groups

### 1

#### Description

First Intervention group: From the third to the seventh day of menstruation, they take two clomiphene 50 mg tablets (100 mg in total) daily, and then from the eighth to the eleventh day of menstruation, they take two 2.5 mg letrozole tablets (5 mg in total). On the 8th and 12th days of the Menstrual cycle Transvaginal ultrasound will be performed to check the number of follicles, the size of the follicles that have grown, and the thickness of the endometrium.If the size of the follicle is more than 18 mm, HCG ampoule is injected from 5000 to 10,000 units depending on the number and size of the follicle.(CLOMIPHENE CITRATE TABLET ORAL 50 mg with OVUMID brand from Iran Hormone Company) (LETROZOLE TABLET ORAL 2.5 mg with LETROFEM brand from Iran Hormone Company) (CHORIONIC GONADOTROPHIN (HUMAN) INJECTION, POWDER, FOR SOLUTION PARENTERAL 5000 [iU] with IVF-C brand from Arman Pharmed Daru company)

#### Category

Treatment - Drugs

### 2

#### Description

Second Intervention group: From the third to the eleventh day, they take two 2.5 mg letrozole tablets daily (5 mg in total) and then from the eighth day, they take two 0.5 mg cabergoline tablets daily until the eleventh day.On the 8th and 12th days of the Menstrual cycle Transvaginal ultrasound will be performed to check the number of follicles, the size of the follicles that have grown, and the thickness of the endometrium.If the size of the follicle is more than 18 mm, HCG ampoule is injected from 5000 to 10,000 units depending on the number and size of the follicle.(LETROZOLE TABLET ORAL 2.5 mg with LETROFEM brand from Iran Hormone Company) (CABERGOLINE TABLET ORAL 0.5 mg with CABERLIN brand from Iran Hormone Company) (CHORIONIC GONADOTROPHIN (HUMAN) INJECTION, POWDER, FOR SOLUTION PARENTERAL 5000 [iU] with IVF-C brand from Arman Pharmed Daru company)

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Jahrom university of medical sciences

##### Full name of responsible person

Jahrom university of medical sciences

##### Street address

ProMotahari St.- After School of Nursing- Jahrom University of Medical Sciences- Pardis Site

##### City

Jahrom  
**Province**  
Fars  
**Postal code**  
۷۴۱۴۸-۴۶۱۹۹  
**Phone**  
+98 71 5433 1521  
**Email**  
Pazhuheshi@jums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Jahrom University of Medical Sciences  
**Full name of responsible person**  
Athar Rasekhjahromi  
**Street address**  
Jahrom-Ostad Motahari Street-After School of Nursing-  
Jahrom University of Medical Sciences-Pardis site.  
**City**  
Jahrom  
**Province**  
Fars  
**Postal code**  
۷۴۱۴۸-۴۶۱۹۹  
**Phone**  
+98 71 5433 1521  
**Email**  
Drrasekh@yahoo.com

#### Grant name

#### Grant code / Reference number

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

#### Title of funding source

Jahrom 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

### 2

#### Sponsor

**Name of organization / entity**  
Jahrom University of Medical Sciences  
**Full name of responsible person**  
Athar Rasekh Jahromi  
**Street address**  
Jahrom-Ostad Motahari Street-After School of Nursing-  
Jahrom University of Medical Sciences-Pardis site.  
**City**

Jahrom  
**Province**  
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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

Jahrom 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**  
Jahrom University of Medical Sciences

#### Full name of responsible person

Athar Rasekh Jahromi

#### Position

Medical doctor(gynecologist)

#### Latest degree

Specialist

#### Other areas of specialty/work

Gynecology and Obstetrics

#### Street address

Jahrom-Ostad Motahari Street-After School of Nursing-  
Jahrom University of Medical Sciences-Pardis site

#### City

Jahrom

#### Province

Fars

#### Postal code

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#### Phone

+98 71 5433 1521

#### Email

Drrasekh@yahoo.com

## Person responsible for scientific inquiries

#### Contact

#### Name of organization / entity

Jahrom University of Medical Sciences

#### Full name of responsible person

Athar Rasekh Jahromi

**Position**

Medical doctor

**Latest degree**

Specialist

**Other areas of specialty/work**

Gynecology and Obstetrics

**Street address**

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Jahrom University of Medical Sciences

**Full name of responsible person**

Athar Rasekh Jahromi

**Position**

Medical doctor

**Latest degree**

Specialist

**Other areas of specialty/work**

Gynecology and Obstetrics

**Street address**

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**Postal code**

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**Phone**

+98 71 5433 1521

**Email**

Drrasekh@yahoo.com

**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is 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**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

Data would be presented according to the jahrom university of medical sciences protocols

**When the data will become available and for how long**

According to the jahrom university of medical sciences protocols

**To whom data/document is available**

According to the jahrom university of medical sciences protocols

**Under which criteria data/document could be used**

According to the jahrom university of medical sciences protocols

**From where data/document is obtainable**

Jahrom university of medical sciences

**What processes are involved for a request to access data/document**

According to the jahrom university of medical sciences protocols

**Comments**