Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Jul 2026

Ovulation induction with clomiphene citrate and letrozole vesus 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 + cabergolineTo 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 ß- 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 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
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Email address
drrasekh@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 vesus 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
ProMotahhari St.- After School of Nursing- Jahrom University of Medical Sciences- Pardis Site
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Jahrom-Ostad Motahari Street-After School of Nursing-Jahrom University of Medical Sciences-Pardis site.
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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
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Phone
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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

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
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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

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Person responsible for updating data

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Position
Medical doctor

Latest degree
Specialist

Other areas of specialty/work
Gynecology and Obstetrics

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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