

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jul 2026

Comparison of the pregnancy rate with clomiphen citrate and letrozole in women with poly-cystic ovarian syndrome

Protocol summary

Study aim

This study was conducted with the aim of comparison the pregnancy rate with clomiphen citrate and letrozole in women with poly-cystic ovarian syndrome.

Design

Phase 2-3 clinical trial with parallel groups which was conducted on 80 women with polycystic ovarian syndrome

Settings and conduct

This study was conducted with the aim of comparison the pregnancy rate with clomiphen citrate and letrozole on 80 women with poly-cystic ovarian syndrome. Patients were randomly assigned into two groups; group 1 receiving 100 mg clomiphen citrate orally and group 2 receiving 10 mg letrozole orally. In both groups the drugs were given on days 3-5 of the menstruation cycle. 1 month after giving the drugs, in both groups the pregnancy rate was determined by measuring the B-HCG serum level and compared together.

Participants/Inclusion and exclusion criteria

Inclusion criteria: one-year infertility; normal semen analysis in the husband Exclusion criteria: thyroid dysfunction; fallopian tube or uterine cavity abnormalities

Intervention groups

Intervention group 1:Receiving 10 mg letrozole orally on days 3-5 of the menstruation cycle Intervention group 2:Receiving 10 mg letrozole orally on days 3-5 of the menstruation cycle

Main outcome variables

Pregnancy Rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180602039952N2**

Registration date: **2018-10-26, 1397/08/04**

Registration timing: **retrospective**

Last update: **2018-10-26, 1397/08/04**

Update count: **0**

Registration date

2018-10-26, 1397/08/04

Registrant information

Name

Farahnaz Farzaneh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 54 3329 5744

Email address

f.farzaneh@zaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-03-21, 1397/01/01

Expected recruitment end date

2018-09-12, 1397/06/21

Actual recruitment start date

2018-03-21, 1397/01/01

Actual recruitment end date

2018-09-22, 1397/06/31

Trial completion date

2018-09-22, 1397/06/31

Scientific title

Comparison of the pregnancy rate with clomiphen citrate and letrozole in women with poly-cystic ovarian syndrome

Public title

Pregnancy rate with clomiphen citrate and letrozole

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
One-year infertility Normal semen analysis in the husband

Exclusion criteria:
Thyroid dysfunction Fallopian tube or uterine cavity abnormalities

Age
From **18 years** old to **40 years** old

Gender
Female

Phase
2-3

Groups that have been masked

- Investigator
- Data analyser

Sample size
Target sample size: **80**
Actual sample size reached: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
Block randomization with blocks of 10. The patients were randomly assigned into 2 groups of 40. Considering the sample size of 80 (40 patients in letrozole group and 40 patients in clomiphen citrate group) , 8 blocks with 10 people were selected; in each block there was 5 cards of letrozole group and 5 cards of clomiphen citrate group. So by selecting each block, 5 people were assigned into each group.

Blinding (investigator's opinion)
Double blinded

Blinding description
The study author and data analyzer were not aware of the patients assignment into study groups

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Zahedan University of Medical Sciences

Street address
Zahedan University of Medical Sciences, Dr Hesabi sq., Daneshgah Blvd.

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Zahedan

Province

Sistan-va-Balouchestan

Postal code
9816743463

Approval date
2016-09-25, 1395/07/04

Ethics committee reference number
IR.ZAUMS.REC.1395. 47

Health conditions studied

1

Description of health condition studied
Polycystic ovarian syndrome

ICD-10 code
E28.2

ICD-10 code description
Polycystic ovarian syndrome

Primary outcomes

1

Description
Pregnancy rate

Timepoint
1 month after giving the drugs

Method of measurement
By measuring the serum level of B-HCG using DiaPlus B-HCG STAT kit

Secondary outcomes
empty

Intervention groups

1

Description
Intervention group 1:Receiving 100 mg clomiphen citrate orally on days 3-5 of the menstruation cycle

Category
Treatment - Drugs

2

Description
Intervention group 2:Receiving 10 mg letrozole orally on days 3-5 of the menstruation cycle

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Ali Ebne Abi Taleb Hospital

Full name of responsible person
Farahnaz Farzaneh

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Khalije Fars Blv, Zahedan
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Zahedan University of Medical Sciences
Full name of responsible person
محسن طاهری
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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

Zahedan 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
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Full name of responsible person
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Position

Assistant professor
Latest degree
Specialist
Other areas of specialty/work
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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

Undecided - It is not yet known if there will be a plan to
make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be 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