Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jul 2026

Investigating the effect of low-dose aspirin on the success rate of ovulation induction in women with polycystic ovary syndrome

Protocol summary

Study aim
Determination of the effect of low-dose aspirin administration on the success rate of ovulation induction in women with polycystic ovary syndrome.

Design
A clinical trial with parallel groups, double-blind, randomized, on 80 patients. Blocks of 4 were used for randomization.

Settings and conduct
Patients suffering from polycystic ovary syndrome disease with the inability to ovulate (both primary and secondary) referred to the women's clinic of Ba'ath Sanandaj Hospital in 1401 who meet the inclusion criteria and do not meet the exclusion criteria.

Participants/Inclusion and exclusion criteria
Enclusion criteria: age 20 to 35 years, body mass index less than 30 kg/m2, suffering from polycystic ovary according to Rotterdam criteria. Exclusion criteria: other causes of infertility, male factor, abnormal thyroid function tests, abnormal prolactin levels, diabetes, the anatomical disorder in hysterosalpingography or laparoscopy, endometriosis.

Intervention groups
The first group: recipients of clomiphene citrate with a dose of 50 to 150 mg from the day of the 3rd cycle to 3 months after ovulation + placebo daily until pregnancy or the end of the study. The second group: received letrozole at a dose of 5 to 7.5 mg from day 3 of the cycle to 3 months after ovulation + a placebo daily until pregnancy or the end of the study. The third group: recipients of clomiphene citrate at a dose of 50 to 150 mg from day 3 of the cycle until 3 months after ovulation + oral aspirin at a dose of 80 mg daily from the third day of the previous menstrual cycle until pregnancy or termination. study The fourth group: recipients of letrozole at a dose of 5 to 7.5 mg from day 3 of the cycle until 3 months after ovulation + oral aspirin at a dose of 80 mg daily from the third day of the previous menstrual cycle until pregnancy or the end of the study.

Main outcome variables
pregnancy

General information

Reason for update
Increase the sample size

Acronym

IRCT registration information
IRCT registration number: **IRCT20221112056477N1**
Registration date: **2022-12-04, 1401/09/13**
Registration timing: **prospective**

Last update: **2023-02-14, 1401/11/25**
Update count: **1**

Registration date
2022-12-04, 1401/09/13

Registrant information

Name
Hosna Liravi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 66 1966 7761

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-01-21, 1401/11/01

Expected recruitment end date
2023-06-22, 1402/04/01

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of low-dose aspirin on the success rate of ovulation induction in women with polycystic ovary syndrome

Public title

The effect of low-dose aspirin on the success rate of ovulation induction in women with polycystic ovary syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 20 to 35 years Body mass index less than 30 kg/m2 Suffering from the polycystic ovary, according to Rotterdam criteria

Exclusion criteria:

Other causes of infertility Male factor Abnormal thyroid function tests Abnormal prolactin levels Diabetes Anatomical disorder in hysterosalpingography or laparoscopy Endometriosis

Age

From **20 years** old to **35 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **120**

More than 1 sample in each individual

Number of samples in each individual: **1**

Each patient will receive one drug plus placebo.

Randomization (investigator's opinion)

Randomized

Randomization description

Considering that there are 4 groups under investigation and each group receives one of A, B, C, or D treatments 4 random blocks are formed as follows: ABCD, ACBD, ADCB, ADBC, ACDB, ABDC, BACD, BCAD, BDCA, BDAC, BCDA, BADC, CBAD, CBDA, CABD, CADB, CDAB, CDBA, DBCA, DBAC, DCBA, DCAB, DABC, DACB, Each time and for every 4 new patients who will enter the study, one of the above blocks will be randomly selected, and based on the order in the selected block, they will receive one of the A, B, C, or D treatments.

Blinding (investigator's opinion)

Double blinded

Blinding description

This is a double-blind study. The patients and the main researcher do not know the type of treatment received by the groups. The statistical analysis will be done by another researcher who is unaware of the type of treatment received by the different groups.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kurdistan University of Medical Sciences

Street address

Besat Hospital, Department of Obstetrics and Gynecology, Sanandaj, Kurdistan, Iran

City

sanandaj

Province

Kurdistan

Postal code

6619667761

Approval date

2022-01-02, 1400/10/12

Ethics committee reference number

IR.MUK.REC.1400.236

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

Ovulation induction

Timepoint

On the 14th day of the menstrual cycle and Every day for the next two weeks

Method of measurement

Serum levels of human chorionic gonadotropin

Secondary outcomes

1

Description

pregnancy

Timepoint

Day 14 of the cycle

Method of measurement

Transvaginal ultrasound

2

Description

Do Quitos

Timepoint

Three times a week

Method of measurement

Transvaginal ultrasound

3

Description

Measurement of human chorionic gonadotropin-beta serum level

Timepoint

two weeks later

Method of measurement

Serum test

4

Description

gestational sac

Timepoint

Six weeks later

Method of measurement

Transvaginal ultrasound

Intervention groups

1

Description

Intervention group: The first group: recipients of clomiphene citrate with a dose of 50 to 150 mg from the day of the 3rd cycle to 3 months after ovulation + placebo daily until pregnancy or the end of the study.

Category

Treatment - Drugs

2

Description

Intervention group: The second group: receiving letrozole at a dose of 5 to 7.5 mg from day 3 of the cycle to 3 months after ovulation + placebo daily until pregnancy or the end of the study.

Category

Treatment - Drugs

3

Description

Intervention group: The third group: recipients of clomiphene citrate at a dose of 50 to 150 mg from day 3 of the cycle until 3 months after ovulation + oral aspirin at a dose of 80 mg daily from the third day of the previous menstrual cycle until pregnancy or termination. study

Category

Treatment - Drugs

4

Description

The third group: recipients of clomiphene citrate at a dose of 50 to 150 mg from day 3 of the cycle until 3 months after ovulation + oral aspirin at a dose of 80 mg daily from the third day of the previous menstrual cycle until pregnancy or termination. study

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat Hospital

Full name of responsible person

Liravi Hosna

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sanandaj University of Medical Sciences

Full name of responsible person

Khaled Rahmani

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6618634683

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research@nkums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source
Sanandaj 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
Sanandaj University of Medical Sciences
Full name of responsible person
Liravi Hosna
Position
Resident
Latest degree
Medical doctor
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is 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
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
The research data will be provided to the requestors without mentioning the personal characteristics of the research participants.
When the data will become available and for how long
After the end of the research and confirmation of the obtained results and obtaining permission from the university, the information will be provided.
To whom data/document is available
Government and private research institutes and people who are interested in research in the studied field.
Under which criteria data/document could be used
In order to continue the research and complete the obtained protocol.

From where data/document is obtainable

Research assistant of the faculty

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

The request will be submitted to the research vice-chancellor of the faculty. If approved, it will be sent to the supervisor, and if approved, the information will be provided to the applicant.

Comments