

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

Inclusion 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)

Phone

+98 66 1966 7761

Email address

liravihosna@gmail.com

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, AD BC, 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
Street address
Pasdaran
City
Sanandaj
Province
Kurdistan
Postal code
7184877699
Phone
+98 87 3328 5911
Email
liravihosna@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Sanandaj University of Medical Sciences
Full name of responsible person
Khaled Rahmani
Street address
Pasdaran
City
Sanandaj
Province
Kurdistan
Postal code
6618634683
Phone
+98 87 3366 4645
Email
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

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Pasdarán

City

Sanandaj

Province

Kurdistan

Postal code

6619667763

Phone

+98 87 3328 5912

Email

liravihosna@gmail.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Sanandaj University of Medical Sciences

Full name of responsible person

Liravi Hosna

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Pasdarán

City

Sanandaj

Province

Kurdistan

Postal code

7184877699

Phone

+98 87 3328 5911

Email

liravihosna@gmail.com

Person responsible for updating data**Contact****Name of organization / entity**

Sanandaj University of Medical Sciences

Full name of responsible person

Liravi Hosna

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Pasdarán

City

Sanandaj

Province

Kurdistan

Postal code

7184877699

Phone

+98 87 3328 5911

Email

liravihosna@gmail.com

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