Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of clomiphene citrate stair-step protocol with standard protocol on ovulation induction and treatment of infertility in women with polycystic ovarian syndrome

Protocol summary

Study aim

To compare clomiphene citrate stair-step protocol with standard protocol on ovulation induction and treatment of infertility in women with polycystic ovarian syndrome

Design

In this single blinded randomized clinical trial, the researcher goes to infertility clinic daily. Each patient who has inclusion criteria to enroll in the study is considered as a sample. Samples were divided into 2 groups A and B by computer random selection. Patients were randomly divided into intervention and control groups based on randomized block method. Total of 60 patients were enrolled.

Settings and conduct

This clinical trial is carried out at the Infertility Clinic of Besat Hospital in Sanandaj. Patients are unaware of how they are grouped and blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Infertility due to polycystic ovarian syndrome resistant to treatment and willingness to participate in the study. Exclusion criterion is age over forty years.

Intervention groups

Intervention group 1: From the third day of menstruation, 50 mg clomiphene is administered daily for 5 days on 14th day of menstruation ultrasound is performed. If the size of the follicles was <12 mm, 100 mg clomiphene is administered daily for another 5 days , on the 20th day of menstruation ultrasound is performed. If the size was<12 mm, for another 5 days, 150 mg of clomiphene is administered daily and on the 25th day of menstruation ultrasound is performed. Intervention group 2: From the third day of menstruation, 50 mg clomiphene is administered daily for 5 days and ultrasound is performed on the 14th day of menstruation. If ovulation is not induced, in the next month protocol repeated with 100 mg , if ovulation not induced, in the next month (the third month) protocol repeated with 150 mg clomiphene.

Main outcome variables

Ovulation induction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190507043502N1**
Registration date: **2019-05-26, 1398/03/05**
Registration timing: **registered_while_recruiting**

Last update: **2020-01-28, 1398/11/08**
Update count: **1**

Registration date

2019-05-26, 1398/03/05

Registrant information

Name

Solmaz Ghasemi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 87 3366 4655

Email address

solmaz.ghasemi@muk.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-22, 1398/03/01

Expected recruitment end date

2019-10-22, 1398/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of clomiphene citrate stair-step protocol with standard protocol on ovulation induction and treatment of infertility in women with polycystic ovarian syndrome

Public title

Comparison of clomiphene citrate stair-step protocol with standard protocol on treatment of infertility

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Infertility due to polycystic ovarian syndrome resistant to treatment willingness to participate in the study

Exclusion criteria:

Age over forty years

Age

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

Gender

Female

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

The researcher goes to the clinic daily. Each patient who has inclusion criteria to enroll in the study is considered as a sample. Samples are divided into 2 groups A and B by computer random selection.Patients are randomly divided into two intervention and control groups based on randomized block method, for example: ABAB / AABB / BBAA.

Blinding (investigator's opinion)

Single blinded

Blinding description

Women in the study are unaware of how they are grouped

Placebo

Not 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

Pasdaran St., Kurdistan University of Medical Sciences

City

Sanandaj

Province

Kurdistan

Postal code

66177-13446

Approval date

2018-12-25, 1397/10/04

Ethics committee reference number

IR.MUK.REC.1397.268

Health conditions studied

1

Description of health condition studied

Ovulation induction

ICD-10 code

N97.0

ICD-10 code description

Female infertility associated with anovulation

Primary outcomes

1

Description

The size of follicles

Timepoint

The days 14, 20, 25 of the cycle

Method of measurement

Transvaginal ultrasonography

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: From the third day of menstruation, 50 mg of clomiphene citrate is administered daily to the patients for 5 days and on 14th day of menstruation ultrasound is performed.If the size of the follicles was less than 12 mm, then 100 mg of clomiphene citrate is administered daily for another 5 days and on the 20th day of the menstruation ultrasound is performed. If the size of the follicles was less than 12 mm then for another 5 days, 150 mg of clomiphene citrate is administered daily to the patients and on the 25th day of menstruation ultrasound is performed.

Category

Treatment - Drugs

2

Description
Intervention group: From the third day of menstruation, 50 mg of clomiphene is administered daily for 5 days, and ultrasound is performed on the 14th day of menstruation.If ovulation is not induced, in the next month from the third day of menstruation, 100 mg of clomiphene is administered daily for 5 days, and ultrasound is performed on the 14th day of menstruation, and if ovulation is not induced, in the next month (the third month) from the third day of menstruation, 150 mg of clomiphene is administered daily for 5 days, and ultrasound is performed on the 14th day of menstruation.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Besat Hospital

Full name of responsible person
Solmaz Ghasemi

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Keshavarz St, Besat Hospital, Sanandaj, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Sanandaj University of Medical Sciences

Full name of responsible person
Vice Chancellor for Research of Kurdistan University of Medical Sciences

Street address
Pasdaran St., Kurdistan University of Medical Sciences, Sanandaj, Iran

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Mozh.zarei@yahoo.com

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
Solmaz Ghasemi

Position
Resident of Obstetrics and Gynecology

Latest degree
Medical doctor

Other areas of specialty/work
Gynecology and Obstetrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Sanandaj University of Medical Sciences

Full name of responsible person
Sholeh Shahgheibi

Position
Professor of Obstetrics and Gynecology

Latest degree
Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for updating data

Contact

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Position
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Latest degree
Medical doctor

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
Yes - There is a plan to make this available

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

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

Clinical Study Report
Yes - There is 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
Not applicable

Title and more details about the data/document
Part of the data on the primary outcome is for sharing.

When the data will become available and for how long
One year after the publication the data will be available.

To whom data/document is available
Researchers working in academic and scientific institutions

Under which criteria data/document could be used
Meta-analysis is allowed on the data of this study.

From where data/document is obtainable
Dr. Solmaz Ghasemi, Pasdaran St., Kurdistan University of Medical Sciences, Sanandaj, Iran,Email: solmaz.ghasemi@muk.ac.ir

What processes are involved for a request to access data/document
After one year of publishing the article and publishing the results, those who need the data of this study, could apply via email.

Comments