

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 2026

Evaluating the effect of combination of Inofolic Supplement and Clomifene and Clomifene alone on infertility treatment in women with polycystic ovarian syndrome

Protocol summary

Study aim

Evaluating the effect of Inofolic Supplement to help infertility treatment in patients with polycystic ovarian syndrome

Design

Patients will be selected by simple random sampling method. Patients will be selected by researcher visiting the infertility clinic daily. After giving the necessary explanation about the study and signing the informed consent form, researcher will give a card to patients from a package containing 80 closed envelopes which contains cards A (intervention group) and B (control group). Patients will be divided into groups A (intervention group) and B (control group) based on the card they received. Sampling continues in two parallel groups until the number of samples completed. Patients have no information about grouping.

Settings and conduct

This clinical trial is carried out at the Infertility Clinic of Besat Hospital in Sanandaj. Patients are unaware of the group they are assigned and they will be kept blind.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Age of 20 to 40 years old, Infertile women with polycystic ovarian syndrome. Non inclusion Criteria: Ovarian surgery history in the past three months, Use of antiepileptic drugs and glucocorticoids, Congenital adrenal hyperplasia, Hypothyroidism, Hyperthyroidism

Intervention groups

Patients in the intervention group will be given clomiphene and inofolic supplement for 3 months and patients in the control group will receive only Clomiphene for 3 months.

Main outcome variables

The number of developed follicles, The number of clinical pregnancies

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190825044605N1**

Registration date: **2019-09-27, 1398/07/05**

Registration timing: **retrospective**

Last update: **2019-09-27, 1398/07/05**

Update count: **0**

Registration date

2019-09-27, 1398/07/05

Registrant information

Name

Khadijeh Ebrahimpour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 87 3328 5890

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-21, 1398/02/01

Expected recruitment end date

2019-09-23, 1398/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effect of combination of Inofolic Supplement and Kломifen and Kломifen alone on infertility treatment in women with polycystic ovarian syndrome

Public title

The effect of Inofolic Supplement on infertility treatment in women with polycystic ovarian syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age range of 20 to 40 years old Infertile women with polycystic ovarian syndrome

Exclusion criteria:

Ovarian surgery history in the past three months Use of antiepileptic drugs and glucocorticoids Congenital adrenal hyperplasia Hypothyroidism Hyperthyroidism

Age

From **20 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be selected by simple random sampling method. Patients will be selected by researcher visiting the infertility clinic daily. After giving the necessary explanation about the study and signing the informed consent form, researcher will give a card to patients from a package containing 80 closed envelopes which contains cards A (intervention group) and B (control group). Patients will be divided into groups A (intervention group) and B (control group) based on the card they received. Sampling continues in two parallel groups until the number of samples completed. Patients have no information about grouping.

Blinding (investigator's opinion)

Single blinded

Blinding description

Both intervention and control groups receive routine infertility treatment but they both are unaware of the group they are assigned and they will be kept blind about the drug type they will receive.

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

Kurdistan University of Medical Sciences, Pasdaran street

City

Sanandaj

Province

Kurdistan

Postal code

66177-13446

Approval date

2019-01-02, 1397/10/12

Ethics committee reference number

IR.MUK.REC.1397.228

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

The number of developed follicles

Timepoint

Two weeks after the intervention

Method of measurement

Using Sonography

2

Description

The number of clinical pregnancies

Timepoint

Third week after intervention

Method of measurement

Based on Beta-HCG and ultrasound confirmation

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients in the intervention group will be given clomiphene and inofolic supplement for 3 months. In the first month of the intervention, 50 mg clomiphene is administered to the patient for 5 days from the third day of menstruation, an inofolic sachets containing 2000 g myoinositol and 200 µg folic acid is administered daily until the end of the month. In the second month of the intervention, 100 mg clomiphene is administered to the patient for 5 days from the third day of menstruation, an inofolic sachets containing 2000 g myoinositol and 200 µg folic acid is administered daily until the end of the month. In the third month of the intervention, 150 mg clomiphene is administered to the patient for 5 days from the third day of menstruation, an inofolic sachets containing 2000 g myoinositol and 200 µg folic acid is administered daily until the end of the month.

Category

Treatment - Drugs

2

Description

Control group: Patients in the control group received only clomiphene for 3 months. In the first month 50 mg clomiphene is administered to the patient for 5 days from the third day of menstruation. In the second month 100 mg clomiphene is administered to the patient for 5 days from the third day of menstruation. In the third month 150 mg clomiphene is administered to the patient for 5 days from the third day of menstruation.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat Hospital

Full name of responsible person

Khadijeh Ebrahimpour

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Besat Hospital, Keshavarz street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sanandaj University of Medical Sciences

Full name of responsible person

Ebrahim Ghaderi

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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

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

Khadijeh Ebrahimpour

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

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Full name of responsible person

Nasrin Soofizadeh

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Assistance Professor of Obstetrics and Gynecology

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Specialist

Other areas of specialty/work

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Person responsible for updating data

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Position

Resident of Obstetrics and Gynecology

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

Some part of the data on the primary outcome can be shared.

When the data will become available and for how long

One year after the publication of the paper 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. Khadijeh Ebrahimpouri, Pasdaran St., Kurdistan University of Medical Sciences, Sanandaj, Iran, Email: k.ebrahimpour@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