Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Evaluating the effect of combination of Inofolic Supplement and Klomifen and Klomifen 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)

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+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 Klomifen and Klomifen 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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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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
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Person responsible for updating data

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Latest degree
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Other areas of specialty/work
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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