Clinical Trial Protocol
Iranian Registry of Clinical Trials

14 Jun 2026

The effect of inofolic powder on fertility in women with polycystic ovary syndrome referred to the gynecology clinic

Protocol summary

Study aim
The effect of inofolic powder on fertility in women with polycystic ovaries
Design
Clinical trial with control group, with parallel groups, randomized, and intervention group, with parallel groups, randomized,. Excel software rand function was used for randomization
Settings and conduct
In the control group, 50 infertile women with polycystic ovary syndrome are treated with metformin and progesterone on days 15 to 25 of the ovarian cycle. Also in the intervention group, 50 infertile women with polycystic ovary syndrome treated with metformin and progesterone on days 15 to 25 of the ovarian cycle, as well as inofolic powder in the form of two sachets per day throughout the month and the study site of the clinic Of women in Ilam province
Participants/Inclusion and exclusion criteria
Women with a history of clinical signs such as oligomenorrhea, irregular menstrual cycles and androgen-induced symptoms, tests and ultrasound confirmed polycystic ovary syndrome And have no confounding factors such as history of ovarian surgery in the last three months, use of antiepileptic drugs and glucocorticoids, congenital adrenal hyperplasia, hypothyroidism, hyperthyroidism
Intervention groups
In the control group, 50 infertile women with polycystic ovary syndrome are treated with metformin and progesterone on days 15 to 25 of the ovarian cycle. Also in the intervention group, 50 infertile women with polycystic ovary syndrome are treated with metformin and progesterone on days 15 to 25 of the ovarian cycle, as well as inofolic powder in the form of two sachets per day throughout the month.
Main outcome variables
Inofolic powder is effective on fertility in women with polycystic ovaries and can increase the size and number of follicles.

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20220308054221N1**
Registration date: **2022-09-20, 1401/06/29**
Registration timing: **registered_while_recruiting**

Last update: **2022-09-20, 1401/06/29**
Update count: **0**
Registration date
2022-09-20, 1401/06/29

Registrant information
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Ehsan Mozfari
Name of organization / entity
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2022-09-20, 1401/06/29
Expected recruitment end date
2022-10-22, 1401/07/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date

empty

Scientific title
The effect of inofolic powder on fertility in women with polycystic ovary syndrome referred to the gynecology clinic

Public title
The effect of inofolic powder on fertility in women with polycystic ovary syndrom

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Women who have a proven history of polycystic ovary syndrome, tests, and ultrasound Clinical signs such as oligomenorrhea, irregular menstrual cycle and androgen-induced symptoms

Exclusion criteria:
History of ovarian surgery in the last three months use of antiepileptic drugs and glucocorticoids congenital adrenal hyperplasia hypothyroidism, hyperthyroidism

Age
From **15 years** old to **50 years** old

Gender
Female

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, due to the lack of access to patients and the lack of a database of patients with polycystic ovaries, it is not possible to select a sample randomly, therefore, within 3 months of attending the women's clinic and meeting the entry and exit criteria, as well as obtaining The satisfaction of the clients with the diagnosis of polycystic ovary samples is collected. Therefore, the selection of the sample at this stage will continue until the completion of the sample volume. Then we randomly assign one patient to the control group and one patient to the intervention group. Patients will not be aware of the assigned group, but they will be aware that they have entered a study and will sign a written consent form. Therefore, the allocation of the sample to the control and intervention groups will be completely random.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Ilam University of Medical Sciences

Street address
Ilam University of Medical Sciences, Pajuhesh Boulevard, Banganjab

City
Ilam

Province
Ilam

Postal code
6939177143

Approval date
2022-05-17, 1401/02/27

Ethics committee reference number
IR.MEDILAM.REC.1401.001

Health conditions studied

1

Description of health condition studied
Polycystic ovary syndrome

ICD-10 code
ICD-10 Cha

ICD-10 code description
ICD-10 Chapter XV: Pregnancy, childbirth and the puerperium

Primary outcomes

1

Description
Percentage of infertile women who have had a positive pregnancy

Timepoint
Positive fertility in the first month or the second month or the third month after starting to use inofolic powder

Method of measurement
Positive B-hcg test and ultrasound

Secondary outcomes

1

Description
Increase the number and size of follicles

Timepoint
The first month, the second month and the third month after the start of inofolic powder

Method of measurement
sonography

Intervention groups

1

Description
case group: under treatment with 500 mg Metformin tablets with the brand name Glucophage twice a day and 5 mg Progesterone tablets with the brand name Medrofem twice a day, both pills on days 15 to 25 of the ovarian cycle and also Lo. Li. Pharma brand Inofolic powder is available in the form of two sachets per day throughout the monthfem are taken twice a day.
Category
Treatment - Drugs

2

Description
Control group: treated with metformin and progesterone on days 15 to 25 of the ovarian cycle. 500 mg metformin tablets with the brand name Glucophage are taken twice a day and 5 mg progesterone tablets with the brand name Medrofem are taken twice a day.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ilam Taleghani Hospital
Full name of responsible person
Dr. Tayebe Rashidian
Street address
NO 1, Khabarnegar Ave, Shahid Beheshti Boulevard
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Deputy of Research and Technology, Ilam University of Medical Sciences, Pajuhesh Blvd.
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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
Ilam University of Medical Sciences
Proportion provided by this source
5
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
Ilam University of Medical Sciences
Full name of responsible person
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Position
student
Latest degree
A Level or less
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available