# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

18 Sep 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**
**Name**
Ehsan Mozfari
**Name of organization / entity**
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Iran (Islamic Republic of)
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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**
Ilam University of Medical Sciences
**Full name of responsible person**
Dr Abbas Maleki
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Deputy of Research and Technology, Ilam University of Medical Sciences, Pajuhesh Blvd.
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info@medilam.ac.ir
**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**
Mohamad Ehsan Mozafari
**Position**
student
**Latest degree**
A Level or less
**Other areas of specialty/work**
General Practitioner
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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