

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison the effects of myo-inositol plus clomiphene citrate with metformin plus clomiphene citrate on induction of ovulation among patients with polycystic ovarian syndrome.

Protocol summary

Study aim

Determination of the efficacy of myo-inositol and clomiphene citrate in comparison with metformin and clomiphene citrate on induction of ovulation and pregnancy rates in patients with polycystic ovary syndrome

Design

single blind parallel three groups of randomized controlled clinical trial

Settings and conduct

Infertility Center, Imam Khomeini Hospital, Mazandaran University of Medical Sciences, Sari, Iran.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Women aged 20-35 year Suffering from polycystic ovary syndrome Anovulation and infertility for one year or more Exclusion criteria: Other condition with hyperandrogenism and anovulation (adrenal, hypophysis or ovarian disorders) Other causes of infertility (male factor or tubal factor) Use of hormones or drugs that affect ovulation

Intervention groups

Intervention 1: Use of Inofolic powder (including myo-inositol 2 gr plus folic acid tab 200 microgram, Shafayab Co from Lolipharma Co), 25 mg twice daily till 12 weeks
Intervention 2: Use of Metformin (tab 500 mg, OSVAH Co, Tehran, Iran), 500 mg three times a day till 12 weeks.
Intervention 3: Use of Clomiphene citrate (tab 50 mg, Iran Hormone Co, Tehran, Iran), 50 mg twice daily from 5 till 9th of menstrual cycle.

Main outcome variables

Ovulation rate

General information

Reason for update

The wrong date was selected by mistake and needs to be corrected

Acronym

IRCT registration information

IRCT registration number: **IRCT20160815029374N3**

Registration date: **2018-11-28, 1397/09/07**

Registration timing: **prospective**

Last update: **2025-07-21, 1404/04/30**

Update count: **1**

Registration date

2018-11-28, 1397/09/07

Registrant information

Name

Marzieh Zamaniyan

Name of organization / entity

Mazandaran University of Medical Sciences, Sari, Iran.

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-01, 1397/09/10

Expected recruitment end date

2019-08-01, 1398/05/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effects of myo-inositol plus clomiphene citrate with metformin plus clomiphene citrate on induction of ovulation among patients with polycystic ovarian syndrome.		Name of ethics committee Ethics committee of Mazandaran University of Medical Science.	
Public title	Effects of myo-inositol on induction of ovulation	Street address	240 Plaque, Third floor, Mazandaran University of Medical Sciences, Joybar street, Sari, Iran
Purpose	Treatment	City	Sari
Inclusion/Exclusion criteria		Province	Mazandaran
Inclusion criteria:	Women aged 20-35 year Suffering from polycystic ovary syndrome Anovulation and infertility for one year or more	Postal code	4815659769
Exclusion criteria:	Other condition with hyperandrogenism and anovulation (adrenal, hypophysis or ovarian disorders) Other causes of infertility (male factor or tubal factor) Use of hormones or drugs that affect ovulation	Approval date	2018-06-27, 1397/04/06
Age	From 20 years old to 35 years old	Ethics committee reference number	IR.MAZUMS.IMAMHOSPITAL.REC.1397.021
Gender	Female	Health conditions studied	
Phase	3	1	
Groups that have been masked	Participant	Description of health condition studied	Diseases of the genitourinary system
Sample size	Target sample size: 164	ICD-10 code	N97; N98
Randomization (investigator's opinion)	Randomized	ICD-10 code description	Female infertility; Complications associated with artificial fertilization
Randomization description	Randomization is done based on the Rearrangement of four blocks before the initiation of treatment cycle by one nurse. In fact, only the nurse knows which patient is under the metformin or myo-inositol treatment, or not. Physicians do not know which patient is undergoing intervention, but patients know about the intervention due to informed consent, therefore, it is not possible to concealed the patients in this group.	Primary outcomes	
Blinding (investigator's opinion)	Single blinded	1	
Blinding description	Reduction of Bias Enhancing Scientific Validity Adherence to Ethical Principles Compliance with International Standards	Description	Ovulation rate
Placebo	Not used	Timepoint	On day 12 and 14 and 20 of cycle
Assignment	Parallel	Method of measurement	Questionnaire
Other design features		Secondary outcomes	
Secondary Ids	empty	1	
Ethics committees		Description	Clinical pregnancy rate
1		Timepoint	Forth weeks after positive pregnancy test
Ethics committee		Method of measurement	Questionnaire
		Intervention groups	
		1	
		Description	Intervention group: Use of Inofolic powedr (including myo-inositol 2 gr plus folic acid tab 200 microgram, Shafayab Co from Lolipharma Co), 25 mg twice daily till 12 weeks.
		Category	

2**Description**

Control group: Use of metformin tablet (Gly-Once, 500 mg, Coshan Farmed Co), three times a day till 12 weeks.

Category

Treatment - Drugs

3**Description**

Intervention group: Use of Clomiphene citrate tablet (Clomid, 50 mg, Iran Hormone Co), 100 mg daily from 5 till 9 of menstruation.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Infertility Center, Imam Khomeini Hospital

Full name of responsible person

Marzieh Zamaniyan

Street address

233 plaque, Ground Floor, IVF ward, Imam Khomeini Hospital, Amir Mazandarani Ave, Sari.

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2**Recruitment center****Name of recruitment center**

Mother Infertility Center

Full name of responsible person

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345 Plaque, Mother Infertility Clinic, Ground floor, Shahriar 3 Department, Farhang Street, Sari.

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Email**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Mazandaran University of Medical Science.

Full name of responsible person

Tahereh Abasi

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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

Mazandaran University of Medical Science.

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**

Infertility Center, Department of Obstetrics and Gynecology, Mazandaran University of Medical Science

Full name of responsible person

Marzieh Zamaniyan

Position

Assistant professor, M.D.

Latest degree

Specialist

Other areas of specialty/work

Reproductive Health

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Person responsible for scientific inquiries

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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

Not applicable

Informed Consent Form

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

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable