Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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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+98 11 3336 5724

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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.

Public title
Effects of myo-inositol on induction of ovulation
Purpose
Treatment
Inclusion/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
Age
From **20 years** old to **35 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant

Sample size
Target sample size: **164**
Randomization (investigator's opinion)
Randomized
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.
Blinding (investigator's opinion)
Single blinded
Blinding description
Reduction of Bias Enhancing Scientific Validity Adherence to Ethical Principles Compliance with International Standards
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Mazandaran University of Medical Science.
Street address
240 Plaque, Third floor, Mazandaran University of Medical Sciences, Joybar street, Sari, Iran
City
Sari
Province
Mazandaran
Postal code
4815659769
Approval date
2018-06-27, 1397/04/06
Ethics committee reference number
IR.MAZUMS.IMAMHOSPITAL.REC.1397.021

Health conditions studied

1

Description of health condition studied
Diseases of the genitourinary system
ICD-10 code
N97; N98
ICD-10 code description
Female infertility; Complications associated with artificial fertilization

Primary outcomes

1

Description
Ovulation rate
Timepoint
On day 12 and 14 and 20 of cycle
Method of measurement
Questionnare

Secondary outcomes

1

Description
Clinical pregnancy rate
Timepoint
Forth weeks after positive pregnancy test
Method of measurement
Questionnare

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

Treatment - Drugs

2

Description
Control group: Use of metrformin 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
Marzieh Zamaniyan
Street address
345 Plaque, Mother Infertility Clinic, Ground floor, Shahriar 3 Department, Farhang Street, Sari.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mazandaran University of Medical Science.
Full name of responsible person
Tahereh Abasi
Street address
242 Plaque, Third floor, Mazandaran University of Medical Sciences, Joybar street, Sari.
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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 Scienc
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 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