Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Jun 2026

Comparison of the adjuvant effect of N-acetylcysteine and metformin in induction of ovulation in infertile women with polycystic ovary syndrome treated with clomiphene citrate

Protocol summary

Study aim

Comparison of adjuvant efficacy of two treatment regimens including metformin and n-acetylcysteine with clomiphene citrate in induction of ovulation and fertility improvement in infertile women with polycystic ovary syndrome

Design

Clinical trial with control group, with parallel groups, single blinded, randomized, phase 3 on 50 patients. In this study, we will use the block randomization method.

Settings and conduct

This randomized clinical trial study will be performed on infertile women with polycystic ovary syndrome. Patients are randomly divided into two groups by block randomization method, one group receiving N-acetylcysteine and the other group receiving metformin. Patients will be unaware of how randomization occurs. In both groups and on days 12 to 16 of the cycle, transvaginal ultrasound will be performed.

Participants/Inclusion and exclusion criteria

Infertile female will enroll the study who aged between 20 and 35 years old with polycystic ovary syndrome and normal hysterosalpingography who are candidate for ovulation induction by normal sperm analysis Exclusion criteria are: Endocrine diseases such as abnormal thyroid and prolactin, using metformin and clomiphene in the previous cycle to induce ovulation, patients who are clomiphene-resistance, allergic reaction with metformin or N-acetylcysteine, simple ovarian cyst, liver disease

Intervention groups

In the first intervention group, n-acetylcysteine 1200 mg (Produced by Shimi Daru Company) will be ordered daily in two divided doses and in the second intervention group, metformin 1500 mg daily (Produced by Shimi Daru Company) in three divided doses from the first day of the cycle for 4 weeks.

Main outcome variables

number of follicles, endometrial thickness, size of follicles, frequency of intrauterine sac

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210310050658N1**
Registration date: **2022-02-11, 1400/11/22**
Registration timing: **prospective**

Last update: **2022-02-11, 1400/11/22**
Update count: **0**

Registration date

2022-02-11, 1400/11/22

Registrant information

Name

Mozhgan Ahmadi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 24 3354 7436

Email address

mozhganahmadi13691990@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-03-11, 1400/12/20

Expected recruitment end date

2022-04-09, 1401/01/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the adjuvant effect of N-acetylcysteine and metformin in induction of ovulation in infertile women with polycystic ovary syndrome treated with clomiphene citrate

Public title

N-acetylcysteine and metformin in induction of ovulation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

aged 20-35 years infertile with polycystic ovary syndrome candidates for ovulation induction spouse with normal sperm analysis with normal hysterosalpingography without tubular pathology

Exclusion criteria:

Endocrine and endocrinological diseases such as thyroid disorders and abnormal prolactin Patients who used metformin and clomiphene more frequently in the previous cycle to induce ovulation Clomiphene resistant patients Pituitary or hypothalamic disorders characterized by low gonadotropin levels Drug allergy to metformin or N Acetyl Cystein Simple ovarian cyst Liver disease

Age

From **20 years** old to **35 years** old

Gender

Female

Phase

3

Groups that have been masked

- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, we will use the block randomization method. The size of all blocks is equal and the block size will be 6 (including 3 participants in the intervention group and 3 participants in the control group) in this two-group experiment. Random allocation software is also used to generate a random sequence of blocks.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, data collectors, outcome assessors, and manuscript writers will be completely unaware of the drug prescribing protocol.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Zanjan University of Medical Sciences

Street address

Zanjan University of Medical Sciences, Jomhori BLV. Azadi Squ. Zanjan

City

Zanjan

Province

Zanjan

Postal code

1435689752

Approval date

2021-03-15, 1399/12/25

Ethics committee reference number

IR.ZUMS.REC.1399.454

Health conditions studied

1

Description of health condition studied

Polycystic ovary syndrome

ICD-10 code

E28.2

ICD-10 code description

Polycystic ovary syndrome

Primary outcomes

1

Description

Number of follicles

Timepoint

Four weeks after the intervention

Method of measurement

Transvaginal ultrasound

2

Description

Endometrial thickness

Timepoint

Four weeks after the intervention

Method of measurement

Transvaginal ultrasound

3

Description

Size of follicles

Timepoint

Four weeks after the intervention

Method of measurement

Transvaginal ultrasound

4

Description

frequency of intrauterine sac

Timepoint

Four weeks after the intervention

Method of measurement

Transvaginal ultrasound

Secondary outcomes

1

Description

positive human chorionic gonadotropin (HCG)

Timepoint

Four weeks after the intervention

Method of measurement

ELIZA test

Intervention groups

1

Description

Intervention group: N-acetylcystein administration (produced by Shimi Daru Company)1200 mg daily in two divided doses from the first day of the cycle for 4 weeks

Category

Treatment - Drugs

2

Description

Intervention group: Metformin (produced by Shimi Daru Company) 1500 mg daily in three divided doses from the first day of the cycle for 4 weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Infertility Clinic of Ayatollah Mousavi Hospital in Zanjan

Full name of responsible person

Mozhgan Ahmadi

Street address

Infertility Clinic, Ayatollah Mousavi Hospital, Gavazang Road, Zanjan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Dr. Alireza Shoghli

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Zanjan University of Medical Sciences Campus, Dr. Yousef Sabouti Blvd., Zanjan

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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

Zanjan 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

Zanjan University of Medical Sciences

Full name of responsible person

Mozhgan Ahmadi

Position

Non-faculty specialist physician

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for updating data

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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
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
Part of the data including the main and secondary outcomes can be shared.

When the data will become available and for how long
Access period starts from 2022

To whom data/document is available
Researchers working in academic and scientific institutions

Under which criteria data/document could be used
Raw data is not available to individuals and upon request, the results of the requested statistical analysis will be available to individuals.

From where data/document is obtainable
Contact the research expert of the Infertility Clinic of Zanjan University to receive the required documents or data.

What processes are involved for a request to access data/document
To submit a request, it is enough to contact the mentioned expert and send a written and signed request to her.

Comments