

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparing pregnancy rate with N-acetyl cysteine plus clomiphene citrate versus clomiphene alone in treatment of polycystic ovary syndrome

Protocol summary

Summary

The aim of clinical trial study was Comparing pregnancy rate with N-acetyl cysteine plus clomiphene citrate versus clomiphene alone in treatment of polycystic ovary syndrome, 70 women referred to Milad infertility center of Mashhad that were diagnosed with polycystic ovary syndrome based on the Rotterdam criteria and had the inclusion criteria for this study. They were chosen and randomly divided into intervention (35 people) and control (35 people) groups. On the third day of the menstrual cycle, after spontaneous menstruation by progesterone, a baseline ultrasonography was performed for all patients. From the third day of the cycle, intervention group received 100 mg Clomiphene (two 50 mg tablets) with 1200 mg N-acetyl cysteine (two 600 mg tablets) produced by Fluid UI MUCIL company for 5 days. The patients in the control group were given only 100 mg clomiphene (two 50 mg tablets) on the third day cycle for 5 days. After taking the medication, the follicles number and diameter and endometrial thickness were examined by transvaginal ultrasonography. After observing a 18 - 20 mm follicle, 5000 units of HCG was injected and 14 days later, the pregnancy was controlled.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016042727638N1**

Registration date: **2016-10-31, 1395/08/10**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-10-31, 1395/08/10

Registrant information

Name

Aghdas Abdorazaghnejad

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 51 3882 8888

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Recruitment status

Recruitment complete

Funding source

Research approved budget from the deputy of research and technology of Mashhad University of Medical Sciences

Expected recruitment start date

2015-11-22, 1394/09/01

Expected recruitment end date

2016-08-22, 1395/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing pregnancy rate with N-acetyl cysteine plus clomiphene citrate versus clomiphene alone in treatment of polycystic ovary syndrome

Public title

The effect of clomiphene N-acetyl cysteine on the pregnancy rate

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: PCO patients having at least two of the three conditions for polycystic ovary syndrome based on

Rotterdam criteria; age over 18 years, openness of at least one tubal patency based on HSG; normal spermogram; willingness to cooperate in the studying
Exclusion criteria: changes in the diagnosis of the patience during the research; hyperprolactinemia; hypothyroidism; existence of other endocrine diseases such as Cushing.

Age

From **18 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

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

Mashhad University of Medical Sciences

Street address

Mashhad University of Medical Sciences, Vakil Abad
Blvd, Azadi Square, Mashhad

City

Mashhad

Postal code

Approval date

2015-09-23, 1394/07/01

Ethics committee reference number

lr.mums.fm.rec.1394.347

Health conditions studied

1

Description of health condition studied

PCO syndrome

ICD-10 code

E28.2

ICD-10 code description

Polycystic ovarian syndrome

Primary outcomes

1

Description

The number of follicle

Timepoint

12th day of the cycle

Method of measurement

Measuring the number of ovarian follicles by transvaginal ultrasonography

2

Description

Follicle diameter

Timepoint

12th day of the cycle

Method of measurement

Measuring the follicle diameter by transvaginal ultrasonography

3

Description

Endometrial thickness

Timepoint

12th day of the cycle

Method of measurement

Measuring the endometrial thickness by transvaginal ultrasonography

4

Description

pregnancy

Timepoint

14 days after the HCG injection into the uterus

Method of measurement

Measurement The BetaHCG testing by blood tests

Secondary outcomes

empty

Intervention groups

1

Description

intervention group: received 100 mg Clomiphene (two 50 mg tablets) with 1200 mg N-acetyl cysteine (two 600 mg tablets) produced by Fluid UI MUCIL company for 5 days

Category

Treatment - Drugs

2

Description

control group: were given only 100 mg clomiphene (two 50 mg tablets) on the third day of the cycle for 5 days

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Milad infertility center

Full name of responsible person

Nyyere Khadem

Street address

East Razi Street, Mashhad

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice President of Research Mashhad University of Medical Sciences

Full name of responsible person

Dr. Mohsen Tafaghodi

Street address

Mashhad University of Medical Sciences, Vakil Abad Blvd, Azadi Square, Mashhad

City

Mashhad

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice President of Research Mashhad University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Mashad University of Medical Sciences

Full name of responsible person

Aghdas Abdolrazagh Nejad

Position

Resident of gynecological surgery, infertility

Other areas of specialty/work

Street address

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Person responsible for scientific inquiries

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Full name of responsible person

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Associate Professor

Other areas of specialty/work

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Position

Resident of gynecological surgery, infertility

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report

empty
Analytic Code
empty
Data Dictionary
empty