

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

N-acetylcysteine as an adjuvant to letrozole for induction of ovulation in infertile women with polycystic ovarian syndrome

Protocol summary

Summary

Objective: To evaluate the effect of N-acetyl-cysteine (NAC), a mucolytic drug with insulin sensitizing properties, as an adjuvant therapy to letrozole in infertile women with polycystic ovarian syndrome (PCOS) Design: randomized clinical trial. Patients: forty infertile women diagnosed with PCOS, with normal TSH and prolactin, normal hysterosalpingographies, and normal spermograms of partners. Interventions: The patients are assigned randomly to receive either letrozole 5 mg/d (group I) or letrozole 5 mg/d and NAC 1.2 g/d (group II) for 5 days starting at day 3 of the cycle. On 14th day of cycle, transvaginal ultrasonography will be performed to evaluate endometrial thickness and follicles properties. If mature follicle (18 mm or larger) detected, hCG will be injected and timed coitus advised 12, 36, and 60 hours later. β -hCG level is checked on day 16 after hCG injection. Outcome measures: ovulation rate, pregnancy rate, and endometrial thickness in each group

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Qazvin University of Medical Sciences (QUMS)

Expected recruitment start date

2014-12-31, 1393/10/10

Expected recruitment end date

2015-12-31, 1394/10/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014050617593N1**

Registration date: **2015-06-16, 1394/03/26**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-06-16, 1394/03/26

Registrant information

Name

Fatemeh Mohebbi

Name of organization / entity

Qazvin University of Medical Sciences

Scientific title

N-acetylcysteine as an adjuvant to letrozole for induction of ovulation in infertile women with polycystic ovarian syndrome

Public title

N-acetylcysteine in treatment of infertile women with polycystic ovarian syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: infertile women with PCOS (according to ESHRE/ASRM criteria) with normal hysterosalpingographies, normal spermograms of partners, and not impaired sexual functions exclusion criteria: ovarian cyst >6 cm, history of asthma or allergy, consumption of any drugs with effects on glucose metabolism during the last 3 months before entering the trial.

Age

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

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **40**

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

Qazvin University of Medical Sciences

Street address

Qazvin University of Medical Sciences, Bahonar Blv.,
Qazvin

City

Qazvin

Postal code

Approval date

2014-12-06, 1393/09/15

Ethics committee reference number

28/20/9537

Health conditions studied

1

Description of health condition studied

infertility in polycystic ovarian syndrome

ICD-10 code

E28.2

ICD-10 code description

polycystic ovarian syndrome

2

Description of health condition studied

ICD-10 code

N97.0

ICD-10 code description

Female infertility associated with anovulation

Primary outcomes

1

Description

ovulation rate

Timepoint

7 days after intervention (14th day of menstrual cycle)

Method of measurement

detecting at least one 18 mm follicle or larger in vaginal
ultrasonography

2

Description

pregnancy rate

Timepoint

23 days after intervention (30th day of menstrual cycle)

Method of measurement

laboratory measurement of hCG- β level

Secondary outcomes

1

Description

endometrial thickness

Timepoint

7 days after intervention (14th day of menstrual cycle)

Method of measurement

measuring endometrial thickness by means of vaginal
ultrasonography (millimeters)

Intervention groups

1

Description

letrozole 2.5 mg oral tablets twice daily, for 5 days
starting on day 3 of the menstrual cycle

Category

Treatment - Drugs

2

Description

letrozole 2.5 mg oral tablets twice daily, plus N-acetyl
cysteine 600 mg oral tablets twice daily, for 5 days
starting on day 3 of the menstrual cycle

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr Dabbaghi's outpatient office

Full name of responsible person

Dr Fatemeh Mohebbi

Street address

Azadi Doctors Building, Azadi Sqr., Qazvin

City

Qazvin

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Ms. Shamekhi

Street address

Qazvin University of Medical Sciences, Bahonar Blv.,
Qazvin

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Qazvin

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Qazvin 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

Qazvin University of Medical Sciences

Full name of responsible person

Fatemeh Mohebbi

Position

OB/GYN Resident

Other areas of specialty/work

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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