

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

12 Jun 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.  $\beta$ -hCG level is checked on day 16 after hCG injection. Outcome measures: ovulation rate, pregnancy rate, and endometrial thickness in each group

#### 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 28 3333 6001

##### Email address

fmohebbi@qums.ac.ir

##### 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

##### 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- $\beta$  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

**City**

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**

**Street address**

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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

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Qazvin University of Medical Sciences, Bahonar Blv.,  
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**Web page address**

## 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*