

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

15 Jul 2026

### Study the effect of N-acetyl Cysteine (NAC) on apoptotic factors in granulosa cells of women with polycystic ovarian syndrome

#### Protocol summary

2016-06-11, 1395/03/22

##### Summary

Imbalanced relation between the apoptosis and the proliferation of ovarian cells and follicular atresia is one of the main problems in the patients with polycystic ovarian syndrome (PCOS). So by using antiapoptotic antioxidants such as N-acetyl cysteine (NAC) we can prevent follicular atresia and find the way to overcome disease signs. 20 PCOS patients (age: 25-35) candidate for IVF cycle will participate randomly in the present study. There will be two groups: (1) NAC groups: patients will take NAC (600mg) three times per day for six weeks. (2): placebo group: patients will take placebo three times per day for six weeks. The collaboration in the present study will be between department of anatomical sciences and IVF center of Shahid Akbarabadi Hospital. Granulosa cells of follicular fluid of patients in IVF cycle will be sorted by using filtering method. In the next step the expression of apoptotic and antiapoptotic genes will be studied by Real Time PCR technique. Patient in our study will be chosen according to Rotterdam criteria. The exclusion criteria are Hyperprolactinemia and thyroid disease. Intervention in the present study is administration of N-acetyl cysteine. Main outcome variables include the expression of mRNA of apoptotic (caspase-3 and Bax) and anti-apoptotic (XIAP and Bcl-2) genes.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016041227353N1**

Registration date: **2016-06-11, 1395/03/22**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

##### Registrant information

###### Name

Reza Shirazi

###### Name of organization / entity

Iran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 8670 4821

###### Email address

shirazi.r@iums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Iran University of Medical Sciences

##### Expected recruitment start date

2016-05-21, 1395/03/01

##### Expected recruitment end date

2017-11-22, 1396/09/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Study the effect of N-acetyl Cysteine (NAC) on apoptotic factors in granulosa cells of women with polycystic ovarian syndrome

##### Public title

Reducing complications and treatment of patients with polycystic ovary syndrome

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria for patients: Diagnosis of PCOS

according to the Rotterdam criteria, aged between 25 and 35 years, the lack of Oral contraceptive pill (OCP) and hormone analogues Apart from progesterone , The use of assisted reproductive medicine at the same dose in all cases, the absence of other systemic diseases known, the first IVF cycle in patients. exclusion criteria for patients : Hyperprolactinemia, thyroid disease, congenital adrenal hyperplasia, testosterone-secreting tumors, Cushing, endometriosis, FSH above 10 IU / L on the third day after menstrual bleeding, Use of drugs that affect the metabolism of carbohydrates, using an analog of the hormone progesterone than three months before entering the study and severe kidney and liver diseases.

**Age**

From **25 years** old to **35 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **30**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Iran University of Medical Sciences

**Street address**

Iran - Tehran- Hemmat Highway-Besides Milad Tower

**City**

Tehran

**Postal code****Approval date**

2016-03-29, 1395/01/10

**Ethics committee reference number**

IR.IUMS.REC.1394.27418

**Health conditions studied****1****Description of health condition studied**

polycystic ovarian syndrome: PCOS

**ICD-10 code**

E28.2

**ICD-10 code description**

Sclerocystic ovary syndrome-Stein-Leventhal syndrome

**Primary outcomes****1****Description**

Apoptosis

**Timepoint**

6 weeks after intervention

**Method of measurement**

Real Time PCR

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Tablets NAC (Alborz Darou Pharmaceutical company) - per tablet dose of 600 mg - by three per day - 6 weeks

**Category**

Treatment - Drugs

**2****Description**

Placebo (Alborz Darou Pharmaceutical company)- three per day to 6 weeks

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Akbar Abadi Hospital

**Full name of responsible person**

Dr.Reza Shirazi

**Street address**

Molavi Street - Paradise Garden Station - St. Mother

**City**

Tehran

**Sponsors / Funding sources****1****Sponsor**

Name of organization / entity

Vice chancellor for research, Iran University of  
Medical Sciences

**Full name of responsible person**

Dr Javad Mousavi

**Street address**

Iran - Tehran- Hemmat Highway-Besides Milad Tower

**City**

Tehran

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Vice chancellor for research, Iran 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**

Iran University of Medical Sciences

**Full name of responsible person**

Zahra Azvan

**Position**

Responsible for projects

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

**Contact**

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PhD

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University of Medical Sciences, medical School,  
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## Person responsible for updating data

**Contact**

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**Position**

Student

**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*