

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

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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

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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

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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

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

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Position

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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