

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Effect of N-acetyl Cysteine(NAC) & Metformin co-treatment on Biochemical factors of follicular fluid, Oocytes and Embryos quality in patients with PCOs and undergoing ICSI treatment

Protocol summary

Summary

1) The study of effect of N-acetyl Cysteine(NAC) & Metformin co-treatment on Biochemical factors of follicular fluid, Oocytes and Embryos quality in patients with PCOs and undergoing ICSI treatment. 2) Through a prospective experimental study designed as a clinical trial, 60 infertile patients diagnosed with PCOS who were referred to IVF Unit of the Reproductive Health Research Center of Gom were enrolled. Overall, considering a 95% confidence interval and 80% power, 60 patients were required as the sample population. 3) Inclusion criteria dictated that the patients needed to fulfill PCOS diagnostic criteria based on the Rotterdam consensus workshop in 2003. That is, in order to be enrolled, each patient needed to have two out of three chronic oligo or anovulation criteria, clinical or biochemical hyperandrogenism or polycystic ovaries at sonography examination. Presence of infertility factors other than anovulation, pelvic organic pathologies, congenital adrenal hyperplasia, thyroid dysfunction, Cushing's syndrome, hyperprolactinemia, androgen secreting neoplasia, diabetes mellitus, severe hepatic or kidney diseases, and active peptic ulcer were considered as exclusion criteria. 4) All patients were advised to avoid any change in their physical activity and nutrition and not to undergo any new pharmacotherapy during the study. Patients were asked to report any possible adverse effects. Patients were divided into four groups considering the similarity of compound confounding variables and randomized in order to minimize the effects of confounding factors through a randomized method. 1) Group-M, cases received treatment with Metformin (started with 500 mg three times daily). 2) Group-N, cases received N-acetyl cysteine, 1.8 gm/day (600 mg three times daily). 3) Group-MN, cases received N-acetyl cysteine, 1.8 gm/day (600 mg three times daily)+ Metformin (started with, 500 mg three times

daily). 4) 2) Group-P, the control group took placebo (ORS, Poursina, Tehran, Iran, batch no.30).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201204159476N1**

Registration date: **2012-08-14, 1391/05/24**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-08-14, 1391/05/24

Registrant information

Name

Ebrahim Cheraghi

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Arak University of Medical Sciences

Expected recruitment start date

2012-07-31, 1391/05/10

Expected recruitment end date

2013-02-28, 1391/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of N-acetyl Cysteine(NAC) & Metformin co-treatment on Biochemical factors of follicular fluid, Oocytes and Embryos quality in patients with PCOs and undergoing ICSI treatment

Public title

Effect of N-acetyl Cysteine(NAC) & Metformin co-treatment in patients with PCOs and undergoing ICSI treatment

Purpose

Basic science

Inclusion/Exclusion criteria

Inclusion criteria: age between 25 to 35 years old and PCOS diagnosed according to Rotterdam criteria (2003).
Exclusion criteria: presence of infertility factors other than anovulation, male infertility; pelvic organic pathologies; congenital adrenal hyperplasia; thyroid dysfunction; Cushing's syndrome; hyperprolactinemia; androgen secreting neoplasia; diabetes mellitus; severe hepatic or kidney diseases and active peptic ulcer.

AgeFrom **25 years** old to **35 years** old**Gender**

Female

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **60****Randomization (investigator's opinion)**

Randomized

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

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Royan institute Ethics Committee

Street address

Banihashem ave.

City

Tehran

Postal code**Approval date**

2012-07-10, 1391/04/20

Ethics committee reference number

EC/91/1041

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

polycystic ovarian syndrome

ICD-10 code

N83.2

ICD-10 code description

E28.2

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

Biochemical factors of follicular fluid

Timepoint

After 2 month

Method of measurement

Lab. kits

2**Description**

Oocyte and embryo quality

Timepoint

After 2 month

Method of measurement

Morphology

3**Description**

Biochemical factors of blood serum

Timepoint

After 2 month

Method of measurement

Lab. kits

Secondary outcomes**1****Description**

Gestation rate

Timepoint

After 3 month

Method of measurement

Lab. kit

Intervention groups

1

Description

Control group- placebo-ORS- 3 per day for 6 week

Category

Placebo

2

Description

Metformin group- 1500 mg/ day -6 week

Category

Treatment - Drugs

3

Description

NAC group- 1800 mg/day - 6 week

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

ACECR Qom of INFERTILITY RESEARCH CENTER

Full name of responsible person

Dr. Zahra Ebrahimi, Gynecologist

Street address

Gom, Sharake Isar, Shabnam ave.

City

Gom

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr. Seyyed Mohammad Shariatzadeh

Street address

Arak, Sardasht

City

Arak

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Arak 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

Qom ACECR Infertility Treatment Highly Specialized Center

Full name of responsible person

Dr, Marzie Aavi Soltani

Position

Gynecologist

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Ebrahim Cheraghi

Position

PhD candidate

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

ACECR qom

Full name of responsible person

seid reza tabatabaei

Position

MSc

Other areas of specialty/work

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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