

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jun 2026

Effect of N-acetyl cysteine on oxidative stress biochemical factors and IVF/ICSI outcomes in women with endometrioma: A randomized, double-blinded, phase III Clinical Trial

Protocol summary

Study aim

To evaluate determine the effect of N-acetyl cysteine on improving oocyte quality, reduction of stress oxidative markers, and ongoing pregnancy rate in endometrioma patients who underwent IVF/ICSI cycles

Design

A clinical trial with a control group (placebo), parallel group, double-blind, randomized, phase 3 on 140 patients, used 10 and 4 permutation blocks for randomization.

Settings and conduct

A total of 140 patients with endometrioma, eligible for the study, who underwent IVF / ICSI cycles, randomized into two groups of intervention and control (placebo) by observing ethical points. This is a double-blind study in the form of patient and researcher blindness.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age between 20 and 42 years old; Ultrasound or laparoscopic diagnosis of moderate to severe endometrioma (endometriosis stage III and IV); Serum AMH levels between 0.7 and 4.5 ng/ml; standard long GnRH and antagonist ovulation stimulation cycle; Body mass index (BMI) <30 kg/m². Non-inclusion criteria: congenital uterine malformations; severe male infertility (TESE, PESA); past medical history of asthma.

Intervention groups

Participants who randomly assigned in the intervention group, during 6 weeks simultaneous to start standard long agonist protocol or E2 priming with antagonist induction, will be received 1200 (2×600) mg of effervescent tablets of NAC daily. Blood will collect before the intervention and at the time of oocyte retrieval, in addition to, follicular fluid will be obtained from the mature follicles. Also, we measure severity of dysmenorrhea by visual analogue scale (VAS) technique.

Main outcome variables

MII oocyte number and quality

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210619051619N1**

Registration date: **2021-10-29, 1400/08/07**

Registration timing: **registered_while_recruiting**

Last update: **2021-10-29, 1400/08/07**

Update count: **0**

Registration date

2021-10-29, 1400/08/07

Registrant information

Name

Parvaneh Afsharian

Name of organization / entity

Royan Institute

Country

Iran (Islamic Republic of)

Phone

+98 21 2356 2674

Email address

p.afsharian@royan-rc.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-13, 1400/01/24

Expected recruitment end date

2023-09-23, 1402/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of N-acetyl cysteine on oxidative stress biochemical factors and IVF/ICSI outcomes in women with endometrioma: A randomized, double-blinded, phase III Clinical Trial

Public title

N-acetyl cysteine and endometrioma

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 20 and 42 years old Ultrasound or laparoscopic diagnosis of moderate to severe endometrioma (endometriosis stage III and IV) Serum AMH levels between 0.7 and 4.5 ng/ml Standard long GnRH and antagonist ovulation stimulation cycle Body mass index (BMI) <30 kg/m²

Exclusion criteria:

Non-inclusion criteria: Congenital uterine malformations Severe male infertility (TESE, PESA) Past medical history of asthma

Age

From **20 years** old to **42 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **140**

Randomization (investigator's opinion)

Randomized

Randomization description

The permuted blocks is method for random allocation. The size of the blocks varies, including 10 blocks and 4 blocks. The allocation ratio is equal in both groups. As soon as the included patient a unique identification code is assigned to the patient and will not change during the study.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants, principle investigator, and healthcare providers do not have information about two study groups.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Royan infertility institute

Street address

Number 12, East Hafez Avenue, Bani Hashem Street, Soleimani Highway, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1665659911

Approval date

2019-07-16, 1398/04/25

Ethics committee reference number

IR.ACECR.ROYAN.REC.1398.111

Health conditions studied

1

Description of health condition studied

Endometrioma

ICD-10 code

N80.1

ICD-10 code description

Endometriosis of ovary

Primary outcomes

1

Description

MII oocyte number and quality

Timepoint

Immediately after oocyte puncture

Method of measurement

Observation of oocytes that were mature at the time of oocyte collection

Secondary outcomes

1

Description

Measurement of TAC oxidative stress marker in blood plasma

Timepoint

Before intervention and 6 weeks after intervention

Method of measurement

ELISA

2

Description

Measurement of SOD oxidative stress marker in blood plasma

Timepoint

Before intervention and 6 weeks after intervention

Method of measurement

ELISA

3

Description

Measurement of TAC oxidative stress marker in follicular fluid

Timepoint

After oocyte puncture

Method of measurement

ELISA

4

Description

Measurement of SOD oxidative stress marker in follicular fluid

Timepoint

After oocyte puncture

Method of measurement

ELISA

5

Description

Cleaved embryo numbers

Timepoint

2-3 days after oocyte puncture

Method of measurement

2-3 days embryo from fertilization

6

Description

Blastocyst numbers

Timepoint

5 days after oocyte puncture and sperm insemination

Method of measurement

The stage the embryo reaches after 5 days in culture from the egg retrieval

7

Description

Clinical pregnancy rate

Timepoint

4-6 weeks after embryo transfer

Method of measurement

The observation of gestational sac on ultrasound examination two-three weeks after positive serum β hCG

8

Description

Fertilization rate

Timepoint

2-5 days after sperm insemination

Method of measurement

Percentage of transformation of micro injected oocytes into two pronuclei embryo

Intervention groups

1

Description

Intervention group: Participants who randomly assigned in the intervention group, during 6 weeks simultaneous to start standard long agonist protocol or antagonist induction, will be received 1200 (2×600) mg of effervescent tablets of NAC daily. Blood will collect before the intervention and at the time of oocyte retrieval (end of 6 week), in addition to, follicular fluid will be obtained from the mature follicles. Also, we will measure severity of dysmenorrhea by visual analogue scale (VAS) technique.

Category

Treatment - Drugs

2

Description

Control group: Participants who randomly assigned to the control group, during 6 weeks simultaneous to start the standard long agonist protocol, or antagonist induction, will be received 1200 (2×600) mg of placebo tablets of NAC daily. Blood will collect before the intervention and at the time of oocyte retrieval, in addition to, follicular fluid will be obtained from the mature follicles. Also, we measure severity of dysmenorrhea by visual analogue scale (VAS) technique.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Royan Institute

Full name of responsible person

Abdolhossein Shahverdi

Street address

Royan alley, East Hafez Avenue, Bani Hashem Street, Soleimani Highway, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1665659911

Phone

+98 21 2356 2211

Fax

+98 21 2230 6481

Email

shahverdi@royaninstitute.org

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Royan Institute

Full name of responsible person

Abdolhossein Shahverdi

Street address

Royan alley, East Hafez Avenue, Bani Hashem Street,
Soleimani Highway, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1665659911

Phone

+98 21 2356 2211

Email

shahverdi@royaninstitute.org

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Royan Institute

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries

Contact**Name of organization / entity**

Royan Institute

Full name of responsible person

Parvaneh Afsharin

Position

Associated professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Genetics

Street address

Royan alley, East Hafez Avenue, Bani Hashem Street,
Soleimani Highway, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1665659911

Phone

+98 21 2356 2674

Email

p.afsharian@royan-rc.ac.ir

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Royan Institute

Full name of responsible person

Parvaneh Afsharian

Position

Associated professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Genetics

Street address

Royan alley, East Hafez Avenue, Bani Hashem Street,
Soleimani Highway, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1665659911

Phone

+98 21 2356 2674

Email

p.afsharian@royan-rc.ac.ir

Person responsible for updating data

Contact**Name of organization / entity**

Royan Institute

Full name of responsible person

Zahra Chekini

Position

Resercher

Latest degree

Master

Other areas of specialty/work

Medical Genetics

Street address

Royan alley, East Hafez Avenue, Bani Hashem Street,
Soleimani Highway, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1665659911

Phone

+98 21 2356 2643

Email

zahra_chekini@ymail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to

make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available