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 cysteineon 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 sever 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 dysmenorea 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 sever 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 folicular fluid
Timepoint
After oocyte puncture
Method of measurement
ELISA

4

Description
Measurement of SOD oxidative stress marker in folicular 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 βhCG

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 dysmenorea 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