

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jun 2026

Effect of N-acetyl cysteine on expression of Oxidation-Reduction genes of (FKBP4 ,PRDX6,NRF1,NRF2,GPX3 and MTHFR) during implantation window in women with Recurrent Implantation Failure: A Randomized, Placebo-Controlled, patient and assessor blinded, Phase 2 Clinical Trial

Protocol summary

Study aim

Effect of N-acetyl cysteine on the expression of Oxidation-Reduction genes of (NRF1, NRF2, GPX3, PRDX6, FKBP4, and MTHFR) during implantation window in women with Recurrent Implantation Failure

Design

A Randomized, Placebo-Controlled, patient and assessor blinded, Phase 2 Clinical Trial

Settings and conduct

Forty infertile women with a diagnosis of RIF referred to Royan Institute, will be included in this study and randomly will be divided into intervention and control groups. At the first step, they will be received 1200 mg of effervescent tablets of N-acetyl cysteine (NAC) daily or placebo about 6 weeks. The endometrial biopsy will be taken from patients by catheter biopsy (Pipelle) on 19-21th day in the cycle prior to IVF transfer procedure. In next cycle, these women will undergo routine infertile treatment and ovulation stimulation for IVF procedure and they will continue to take NAC or placebo.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age between 20 and 40 years old; at least twice implantation failure; BMI in the normal range. Patients prescribed drugs such as folic acid, iron, multivitamins, and supplements generally equal status. Exclusion criteria: Irregular menstrual cycle, taking hormonal drugs except thyroid medication, patients with abnormal karyotype or chromosomal disorders; patients who have coagulation problems.

Intervention groups

Intervention group: receive 1200 mg of effervescent tablets of N-acetyl cysteine (NAC) daily about 6 weeks. Control group: receive 1200 mg of effervescent tablets of placebo daily about 6 weeks.

Main outcome variables

Evaluation of Gene expression related to implantation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150831023831N2**

Registration date: **2018-04-14, 1397/01/25**

Registration timing: **retrospective**

Last update: **2018-04-14, 1397/01/25**

Update count: **0**

Registration date

2018-04-14, 1397/01/25

Registrant information

Name

Parvaneh Afsharian

Name of organization / entity

Royan Institute

Country

Iran (Islamic Republic of)

Phone

+98 21 2356 2674

Email address

pafshar@royaninstitute.org

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2015-05-22, 1394/03/01

Expected recruitment end date

2017-02-19, 1395/12/01

Actual recruitment start date

2015-07-30, 1394/05/08

Actual recruitment end date

2016-04-24, 1395/02/05

Trial completion date

empty

Scientific title

Effect of N-acetyl cysteine on expression of Oxidation-Reduction genes of (FKBP4 ,PRDX6,NRF1,NRF2,GPX3 and MTHFR) during implantation window in women with Recurrent Implantation Failure: A Randomized, Placebo-Controlled, patient and assessor blinded, Phase 2 Clinical Trial

Public title

Effect of N-acetyl cysteine on expression of Oxidation-Reduction genes during implantation window in women with Recurrent Implantation Failure

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 20 and 40 years At least twice implantation failure BMI in the normal range Patients prescribed drugs such as folic acid, iron, multivitamins, and supplements generally equal status

Exclusion criteria:

Irregular menstrual cycle Taking hormonal drugs except thyroid medication Patients with abnormal karyotype or chromosomal disorders Patients who have coagulation problems

Age

From **20 years** old to **40 years** old

Gender

Female

Phase

2

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **44**

Actual sample size reached: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Permuted Block Randomization

Blinding (investigator's opinion)

Double blinded

Blinding description

Patient and assessor are blinded

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic Committee of Royan Institute

Street address

Hafez St, Bani Hashem St, Resalat Ave

City

Tehran

Province

Tehran

Postal code

16635148

Approval date

2017-12-17, 1396/09/26

Ethics committee reference number

IR.ACECR.ROYAN.REC.IR.ACECR.ROYAN.REC.1396.56

Health conditions studied

1

Description of health condition studied

Female Infertility

ICD-10 code

N97

ICD-10 code description

Female infertility

Primary outcomes

1

Description

Gene expression related to implantation

Timepoint

9 weeks after intervention

Method of measurement

Real-time PCR

Secondary outcomes

1

Description

Clinical pregnancy

Timepoint

2 weeks after Embryo Transfer

Method of measurement

Measurement of quantitative serum β -hCG

Intervention groups

1

Description

Intervention group: administer 1200 mg of effervescent tablets of N-acetyl cysteine (NAC) daily about 6 weeks

Category

Treatment - Drugs

2

Description

Control group: administer 1200 mg of effervescent tablets of placebo daily about 6 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

پژوهشگاه رویان

Full name of responsible person

دکتر پروانه افشاریان

Street address

Eastern Hafez street, Bani Hashem square, Resalat Highway

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pafshar@royaninstitute.org

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Royan Institute

Full name of responsible person

Dr. Parvaneh Afsharian

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Grant name

Grant code / Reference number

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

No

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

Dr. Parvaneh Afsharian

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Biology

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

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Other areas of specialty/work

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Province

Tehran

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