

# 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  $\beta$ -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

##### City

Tehran

##### Province

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##### Postal code

16635148

##### Phone

+98 21 2356 2674

##### Fax

+98 21 2230 6481

##### Email

pafshar@royaninstitute.org

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Royan Institute

##### Full name of responsible person

Dr. Parvaneh Afsharian

##### Street address

Eastern Hafez street, Bani Hashem square, Resalat Highway

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##### Phone

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##### Fax

+98 21 2230 6481

##### Email

pafshar@royaninstitute.org

##### 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 scientific inquiries

#### Contact

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Dr. Parvaneh Afsharian

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**Person responsible for updating data****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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Highway**City**

Tehran

**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