

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jul 2026

### Evaluation of the effect of N-Acetyl cysteine on sperm parameters, sperm chromatin and oxidative s

#### Protocol summary

##### Summary

The aim of this study was to evaluate the outcome of N-acetyl-L-cysteine (NAC), as an antioxidant on semen quality, protamine deficiency, DNA fragmentation, reactive oxygen species (ROS) and fertility in individuals with varicocele following varicocelectomy. The study included 35 infertile men with varicocele grade II and III who were referred to Isfahan fertility and infertility center for varicocelectomy. This study was designed similar to a double blind clinical trial that patients and researchers were blinded to type of treatment. This individuals were randomly divided into control (n=20) and NAC (n=15) groups. In the control group, the individuals received placebo post varicocelectomy. In the treatment group or NAC group, the individuals received three tablets of NAC post varicocelectomy (200 mg daily) for three months. Semen parameters (according World Health Organization (WHO) criteria), protamine content (Chromomycin A3), DNA Fragmentation (TUNEL) and ROS statuses (DCFH-DA and flow cytometry) were assessed before and three months after varicocelectomy.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201508177223N5**

Registration date: **2015-10-19, 1394/07/27**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2015-10-19, 1394/07/27

##### Registrant information

###### Name

Mohammad Hossein Nasr-Esfahani

##### Name of organization / entity

Royan Institute (Royan Institute for Biotechnology)

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 9501 5688

##### Email address

mh\_nasr@med.mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Royan Institute

##### Expected recruitment start date

2012-05-14, 1391/02/25

##### Expected recruitment end date

2014-07-02, 1393/04/11

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of the effect of N-Acetyl cysteine on sperm parameters, sperm chromatin and oxidative s

##### Public title

The effect of N-Acetyl cysteine on sperm function, after Varicocelectomy

##### Purpose

Health service research

##### Inclusion/Exclusion criteria

Inclusion criteria: Infertile men with primary infertility and left-sided varicocele (grade II and III) and without female factor infertility. Exclusion criteria: Men with grade I varicocele, Azoospermia, leukocytospermia, anatomical disorders, consumption of drug and occupational exposure

##### Age

From **20 years** old to **45 years** old

**Gender**

Male

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **35**

**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**

Ethic Committee of Royan Institute

**Street address**

Hafez St, Baniha shem St, Resalat Ave, Tehran, Iran,  
Royan Institute

**City**

Tehran

**Postal code**

**Approval date**

2015-09-07, 1394/06/16

**Ethics committee reference number**

IR.ACECR.ROYAN.REC.1394.30

**Health conditions studied**

1

**Description of health condition studied**

Male factor infertility

**ICD-10 code**

N46

**ICD-10 code description**

Male infertility

**Primary outcomes**

1

**Description**

Sperm motility

**Timepoint**

In day of surgery

**Method of measurement**

Optical microscope, based WHO criteria (2010)

2

**Description**

Sperm concentration

**Timepoint**

In day of surgery

**Method of measurement**

Optical microscope, based WHO criteria (2010)

3

**Description**

Sperm morphology

**Timepoint**

In day of surgery

**Method of measurement**

Optical microscope, based WHO criteria (2010)

4

**Description**

DNA fragmentation

**Timepoint**

In day of surgery

**Method of measurement**

Fluorescent microscope

5

**Description**

Percentages of ROS positive sperm

**Timepoint**

In day of surgery

**Method of measurement**

flow cytometry

6

**Description**

Protamine deficiency

**Timepoint**

In day of surgery

**Method of measurement**

Fluorescent microscope

7

**Description**

Pregnancy outcome

**Timepoint**

3 months post-surgery

**Method of measurement**

phone

**Secondary outcomes**

empty

## Intervention groups

### 1

#### Description

Intervention group or NAC group: the individuals with varicocele received three tablets of NAC post varicocelectomy (200 mg daily) for three months.

#### Category

Treatment - Drugs

### 2

#### Description

Control group: The individuals with varicocele received placebo after varicocelectomy.

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Isfahan Fertility and Infertility Center

##### Full name of responsible person

Mohammad Hossein Nasr-Esfahani

##### Street address

Salman Farsi St, Isfahan, Iran,

##### City

Isfahan

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Royan Institute

##### Full name of responsible person

Abdolhossein Shahverdi

##### Street address

Hafez St, Banihashem St, Resalat Ave, Tehran, Iran,  
Royan Institute

##### City

Tehran

#### 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

*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

Royan Institute (Royan Institute for Biotechnology)

##### Full name of responsible person

Mohammad Hossein Nasr-Esfahani

##### Position

Professor

##### Other areas of specialty/work

##### Street address

Royan St, Salman St, KHorasgan, Isfahan, Iran

##### City

Isfahan

##### Postal code

##### Phone

+98 31 9501 5688

##### Fax

##### Email

mh\_nasr@med.mui.ac.ir

##### Web page address

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Royan Institute (Royan Institute for Biotechnology)

##### Full name of responsible person

Mohammad Hossein Nasr-Esfahani

##### Position

Professor

##### Other areas of specialty/work

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## Person responsible for updating data

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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*