

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

Street address

Royan St, Salman St, KHorasgan, Isfahan, Iran,

City

Isfahan

Postal code

Phone

+98 95015688

Fax

Email

mh_nasr@med.mui.ac.ir

Web page address

Person responsible for updating data

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

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