

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jul 2026

### Evaluation of the effects of N-Acetyl cysteine on sperm parameters, biochemical-hormonal factors, chromatin integrity and NRF2, HSPA2 genes expression in the terato-astenozoospermic men.

#### Protocol summary

Registration timing: **registered\_while\_recruiting**

##### Study aim

Evaluation of the effects of N-Acetyl cysteine on sperm parameters, biochemical-hormonal factors, chromatin integrity and NRF2, HSPA2 genes expression in the terato-astenozoospermic men.

Last update: **2018-03-14, 1396/12/23**

Update count: **0**

##### Registration date

2018-03-14, 1396/12/23

##### Design

This study was designed based on a clinical trial in which patients and researchers are aware of the type of treatment. Individuals in the NAC group (daily treatment group) receive three NAC tablets daily at 200 mg per day for three months. The control group was the same patients before taking the medication.

##### Registrant information

###### Name

**Name of organization / entity**

###### Country

Iran (Islamic Republic of)

###### Phone

+98 25 3270 0155

###### Email address

rahil.janatifar@srbiau.ac.ir

##### Settings and conduct

This study was performed on 50 infertile patients with terato-astenozoospermia referred to Qom Fertility and Infertility Center for Treatment.

##### Recruitment status

**Recruitment complete**

##### Participants/Inclusion and exclusion criteria

Entry criteria: normal anatomy of the genital area; infertility due to teratology - asthenospermia WHO2010 criteria

##### Funding source

Qom fertility and infertility center

##### Intervention groups

Participant: Those who are invited to participate in the study are categorized in the treatment group after obtaining informed consent. The control group is the same patients before taking the medication.

##### Expected recruitment start date

2018-02-13, 1396/11/24

##### Expected recruitment end date

2018-09-15, 1397/06/24

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Main outcome variables

Sperm Morphology, Sperm Motility, Sperm Concentration, DNA Fragmentation, Antioxidant Enzyme Activity, Gene Expression

##### Trial completion date

empty

#### General information

##### Scientific title

Evaluation of the effects of N-Acetyl cysteine on sperm parameters, biochemical-hormonal factors, chromatin integrity and NRF2, HSPA2 genes expression in the terato-astenozoospermic men.

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20170830035998N4**

Registration date: **2018-03-14, 1396/12/23**

##### Public title

Evaluation of the effects of N-Acetyl cysteine on sperm parameters, chromatin and genes expression in the terato-astenozoospermic men.

#### **Purpose**

Treatment

#### **Inclusion/Exclusion criteria**

##### **Inclusion criteria:**

Entry criteria: normal anatomy of the genital area; infertility due to teratology - asthenospermia WHO2010 criteria

##### **Exclusion criteria:**

Exclusion Criteria: Genital infection during the study; systemic medication for other infections; intake of dietary supplements 3 months before study; positive history of contact with chemical substances, solvents and inorganic substances; specimens from subjects with known etiology (varicocele, cryptorchidism, urinary tract infection, trauma, chemotherapy and etc.); individuals younger than 20 years or older than 40 years old; Individuals with varicocele; prostatitis; epididymitis; orchidism; mumps; testicular trauma; hyperthyroidism; hypothyroidism; diabetes; thalassemia major; genetic disorders affecting infertility (Klinefelter , Noonan syndrome , microdeletion of chromosome Y, the mitochondrial DNA mutations); history of hernia surgery; vasectomy; consumption of antioxidant drugs

#### **Age**

From **25 years** old to **40 years** old

#### **Gender**

Male

#### **Phase**

2

#### **Groups that have been masked**

- Participant

#### **Sample size**

Target sample size: **50**

#### **Randomization (investigator's opinion)**

N/A

#### **Randomization description**

#### **Blinding (investigator's opinion)**

Not blinded

#### **Blinding description**

#### **Placebo**

Not used

#### **Assignment**

Single

#### **Other design features**

### **Secondary Ids**

empty

### **Ethics committees**

#### 1

##### **Ethics committee**

###### **Name of ethics committee**

Ethics committee of Qom Azad University

###### **Street address**

NO.15, Khordad Ave., Qom Azad university

##### **City**

Qom

##### **Province**

Ghous

##### **Postal code**

3719198195

##### **Approval date**

2018-01-22, 1396/11/02

##### **Ethics committee reference number**

IR.IAU.Qom.REC.1396.55

### **Health conditions studied**

#### 1

##### **Description of health condition studied**

Terato-Asthenozoospermia

##### **ICD-10 code**

N46

##### **ICD-10 code description**

Male infertility

### **Primary outcomes**

#### 1

##### **Description**

sperm morphology

##### **Timepoint**

before and after taking drug

##### **Method of measurement**

Optical microscope, based WHO criteria (2010)

#### 2

##### **Description**

Sperm motility

##### **Timepoint**

before and after taking drug

##### **Method of measurement**

Optical microscope, based WHO criteria (2010)

#### 3

##### **Description**

Sperm concentration

##### **Timepoint**

before and after taking drug

##### **Method of measurement**

Optical microscope, based WHO criteria (2010)

#### 4

##### **Description**

DNA fragmentation

##### **Timepoint**

before and after taking drug

##### **Method of measurement**

Fluorescent microscope

## 5

### **Description**

Protamine deficiency

### **Timepoint**

before and after taking drug

### **Method of measurement**

Fluorescent microscope

## 6

### **Description**

antioxidant enzymes

### **Timepoint**

before and after taking drug

### **Method of measurement**

spetophotometry

## 7

### **Description**

gene expression

### **Timepoint**

before and after taking drug

### **Method of measurement**

RT- PCR

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention group or NAC group:received three tablets of NAC(200 mg daily) for three months.

#### **Category**

Treatment - Drugs

### 2

#### **Description**

Control group:before received three tablets of NAC(200 mg )

#### **Category**

Treatment - Drugs

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

infertility center of Qom

##### **Full name of responsible person**

Dr.rahil janatifar

##### **Street address**

Infertility Treatment Center, College of Jihad, Imam Khomeini Town, Islami Square, Shabnam Ave.

##### **City**

Qom

#### **Province**

Ghoom

#### **Postal code**

02532700154

#### **Email**

janatifar@acecr.ac.ir

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Infertility Center of Qom

##### **Full name of responsible person**

Dr.Rahil Janatifar

##### **Street address**

Qom.Infertiliy Center of Qom

##### **City**

Qom

##### **Province**

Ghoom

##### **Postal code**

02532700154

##### **Email**

Rahiljanati2016@gmail.com

#### **Grant name**

#### **Grant code / Reference number**

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

Yes

#### **Title of funding source**

Infertility Center of Qom

#### **Proportion provided by this source**

100

#### **Public or private sector**

Private

#### **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**

Infertility Center of Qom

##### **Full name of responsible person**

Dr.Rahil Janatifar

##### **Position**

PhD Student Research of Develoment Biology

##### **Latest degree**

Master

##### **Other areas of specialty/work**

##### **Street address**

Qom.Infertiliy Center of Qom

##### **City**

Qom

##### **Province**

Ghous  
**Postal code**  
02532700154  
**Phone**  
+98 25 3270 0155  
**Fax**  
**Email**  
janatifar@acecr.ac.ir  
**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Iranian academic center for education culture and research

**Full name of responsible person**  
Rahil Janatifar

**Position**  
PhD Student Research of Development Biology

**Latest degree**  
Master

**Other areas of specialty/work**  
Others

**Street address**  
Infertility Treatment Center, College of Jihad, Imam Khomeini Town, Islami Square, Shabnam Ave.

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+98 25 3270 0154

**Email**  
janatifar@acecr.ac.ir

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Iranian academic center for education culture and research

**Full name of responsible person**  
Rahil Janatifar

**Position**  
PhD Student Research of Development Biology

**Latest degree**  
Master

## Other areas of specialty/work

Others

### Street address

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### Phone

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### Fax

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### Email

janatifar@acecr.ac.ir

## 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

Yes - There is a plan to make this available

### Clinical Study Report

Yes - There is a plan to make this available

### Analytic Code

Yes - There is a plan to make this available

### Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

### Title and more details about the data/document

The main consequences can be used

### When the data will become available and for how long

The interval after the entry of the article and the results

### To whom data/document is available

A portion of the data may be provided to the Urologist

### Under which criteria data/document could be used

Check the effects of the drug

### From where data/document is obtainable

Infertility Center, Qom University Jihad

### What processes are involved for a request to access data/document

Data and documentation can be used after taking the drug and reviewing the results and registering the article

### Comments