

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

Ghous

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

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City

Qom

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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

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Phone
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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

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

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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
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Other areas of specialty/work

Others

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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