

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation the effects of Vitamin E and selenium on the expression of nox5 and HSPA2 in astheniteratozoospermia men

Protocol summary

Study aim

Evaluation the effects of Vitamine E and Selenium on the expression of Nox5 and HSPA2 in Astheniteratozoospermia men

Design

The treated group receives vitamin E and selenium for 3 months and the placebo group receives placebo for three months.

Settings and conduct

This study is double-blind, randomized, placebo-controlled trial study. The treated group received vitamin E and selenium for 3 months and the placebo group received placebo for 3 months. Variables are measured and compared in two groups before and after treatment.

Participants/Inclusion and exclusion criteria

Infertile men with teratosthenozoospermia aged 20 to 55 years old.

Intervention groups

Treated and placebo groups. The treatment group included 30 infertile men with teratosthenozoospermia who received daily vitamin E (400 IU) in combination with selenium (200µg) and the placebo group consisted of 30 infertile men with teratosthenozoospermia who received two placebo tablets (same color) daily for three months.

Main outcome variables

Assessment of Sperm Parameters; Apoptosis and Sperm Protamine Deficiency; HSPA2 assay; NOX5; Intracellular Superoxide Anion

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140409017210N2**

Registration date: **2021-06-04, 1400/03/14**

Registration timing: **retrospective**

Last update: **2021-06-04, 1400/03/14**

Update count: **0**

Registration date

2021-06-04, 1400/03/14

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8800 0659

Email address

ivfyazd@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2014-06-22, 1393/04/01

Expected recruitment end date

2016-06-21, 1395/04/01

Actual recruitment start date

2014-06-22, 1393/04/01

Actual recruitment end date

2016-06-21, 1395/04/01

Trial completion date

2016-06-21, 1395/04/01

Scientific title

Evaluation the effects of Vitamin E and selenium on the expression of nox5 and HSPA2 in astheniteratozoospermia men

Public title

Evaluation the effects of Vitamin E and selenium on the expression of nox5 and HSPA2 in infertile men

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Infertile men with asthenoteratozoospermia (ATZ) with normal morphology lower than 4% and total motility lower than 40%

Exclusion criteria:
Cases with leukocytospermia (>1×10⁶ WBC/mL)
Oligospermia Varicocele Cancer Endocrine disorders
Genital tract infection Autoimmune disease
Cryptorchidism Smoking or alcohol consumption Patients who received chemotherapy or radiotherapy Patients who received recent antioxidant intake Azoospermia

Age
From **20 years** old to **55 years** old

Gender
Male

Phase
N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**
Actual sample size reached: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple Random Sampling. The study population is infertile men with teratostenozoospermia. Each participant randomly enters one of the study groups (placebo or treatment) and will receive two packs of pills in different colors from the doctor who is unaware of their contents. Researchers, impact evaluators and data analysts are also unaware of the assignment of the study group and the record book is in the hands of the doctor until the end of the study. The treatment group receives a daily supplement of vitamin E (400 IU) in combination of selenium (200µg) and the placebo group receives two caplet of placebo for 3 months. Also, all patients will be followed up by researchers throughout the study.

Blinding (investigator's opinion)
Double blinded

Blinding description
All participants, researchers, outcome evaluators, and data analysts are blind to the intervention until the study is completed. Each participant randomly enters one of the study groups (placebo or under treatment) and will receive two packs of pills in different colors from the doctor, which the doctor is unaware of its content. Researchers, impact evaluators and data analysts are also unaware of the assignment of the study group and the record book is in the hands of the doctor until the end of the study.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Sadoughi University of Medical Sciences and Health Services

Street address

Safaieh - Timsar Fallahi Street

City

Yazd

Province

Yazd

Postal code

8916877391

Approval date

2014-09-16, 1393/06/25

Ethics committee reference number

342

Health conditions studied

1

Description of health condition studied

Infertile asthenoteratozoospermia men

ICD-10 code

N46

ICD-10 code description

Diseases of male genital organs

Primary outcomes

1

Description

Sperm concentration

Timepoint

At the beginning of the study (before the intervention) and three months later

Method of measurement

According to WHO 2010 guidelines

2

Description

Sperm motility

Timepoint

At the beginning of the study (before the intervention) and three months later

Method of measurement

According to WHO 2010 guidelines

3

Description

Sperm morphology

Timepoint

At the beginning of the study (before the intervention) and three months later

Method of measurement

Using Papanicolaou staining and according to WHO 2010 guidelines

4

Description

Sperm viability

Timepoint

At the beginning of the study (before the intervention) and three months later

Method of measurement

Using Eosin Nigrosin staining and according to WHO 2010 guidelines

5

Description

Sperm apoptosis

Timepoint

At the beginning of the study (before the intervention) and three months later

Method of measurement

By flow cytometry and according to WHO 2010 guidelines

6

Description

Sperm protamine deficiency

Timepoint

At the beginning of the study (before the intervention) and three months later

Method of measurement

CMA3 staining and fluorescence microscopy and according to WHO 2010 guidelines

7

Description

Intracellular superoxide anion

Timepoint

At the beginning of the study (before the intervention) and three months later

Method of measurement

By flow cytometry

8

Description

HSPA2 positive sperm

Timepoint

At the beginning of the study (before the intervention) and three months later

Method of measurement

By flow cytometry

9

Description

NOX positive sperm

Timepoint

At the beginning of the study (before the intervention) and three months later

Method of measurement

By flow cytometry

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Treatment group received a daily supplement of vitamin E (400 IU) in combination of selenium (200µg)

Category

Treatment - Drugs

2

Description

Placebo group: Take two placebo tablets daily, which look similar to vitamin E and selenium in the treated group, for three months.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Yazd Reproductive Sciences Research Institute, Infertility Therapy Research Center

Full name of responsible person

Parvin Sabeti

Street address

Safaieh , Timsar Fallahi Street

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Fax

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Web page address

<http://web.ssu.ac.ir>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Dr. Masoud Mirzaei

Street address

Shohada Gomnam Boulevard, Professor Hesabi
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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Yazd University of Medical Sciences

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**

Sanandaj University of Medical Sciences

Full name of responsible person

Parvin Sabeti

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Anatomy

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Position

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Ph.D.

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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Position

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is 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

Title and more details about the data/document

Information on the main outcome

When the data will become available and for how long

After printing the results

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

For research work

From where data/document is obtainable

Parvin Sabeti is a member of the faculty of Sanandaj University of Medical Sciences

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

Parvin Sabeti, Sanandaj University of Medical Sciences, School of Medicine, Department of Anatomy

Comments