Clinical Trial Protocol
Iranian Registry of Clinical Trials

23 Jun 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 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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Yazd
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Postal code
8916877391
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+98 35 3824 7085
Fax
Email
yazd-rsi@ssu.ac.ir
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 Boulevard
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8916978477
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yazd-rsi@ssu.ac.ir
Web page address
http://web.ssu.ac.ir

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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Person responsible for updating data

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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