Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of supplementation with selenium-enriched saccharomyces cervisiae yeast on sperm parameters, serum levels of androgens, sexual function, and quality of sexual life in oligoasthenoteratozoosperm infertile men: A triple-blind randomized controlled clinical trial

Protocol summary

Study aim

Determination of the effect of selenium-enriched yeast on sperm parameters, serum androgens, sexual function, and quality of sexual life in oligoasthenoteratozoospermia infertile men in comparison with placebo

Design

The controlled clinical trial, with two parallel arms, triple-blind, randomized, phase 3 on 80 patients. RAS (Random Allocation Software) will be used for randomization.

Settings and conduct

The eligible infertile men referred to infertility clinics affiliated to Tabriz University of Medical Sciences and their spouses will be visited first by a gynecologist and urologist. Participants will be randomly assigned to two groups of selenium-enriched yeast supplements and placebos using a random block method with an allocation ratio of 1:1, which are exactly the same in shape, color and weight. The researcher, participant, data analyst, and outcome assessor will be blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria: An infertile married man with idiopathic oligoasthenoteratozoospermia for at least one year, Age 20 to 40 years, No problem in wife fertility, Non-addiction to alcohol and substance abuse. Exclusion criteria: Azoospermia, Infectious disease and anatomical abnormalities of the genital tract, Varicocele-related infertility, pelvic surgeries or need to do so, cancers, and other chronic diseases,

Intervention groups

The first group will receive one 250 mg capsule of selenium-enriched yeast containing 200 micrograms of organic selenium daily and taken with food for 3 months. The second group will receive 250 mg placebo capsules containing yeast. The placebo will be taken with the same prescription as the selenium capsule.

Main outcome variables

Changes in semen parameters (number, morphology, motility); Serum levels of androgens; Mean sexual function score; Quality of sex life score after intervention

General information

Reason for update

1- Due to the fact that the number of smokers infertile males is high and including the criterion of non-smoking will cause the loss of a high percentage of samples, according to the research group, it was decided to remove this criterion and instead stratification of study groups based on this criterion. Stratification will be done so that the number of smokers in both study groups is equal and its confounding effect is eliminated. 2- Considering that due to the retirement of the esteemed urologist colleague, the sampling status of the project is suspended and fortunately in recent days he has entrusted the cooperation in his project to another urologist who is an assistant professor at the university and considering accepting cooperation from him, sampling will be started in April. Therefore, please the start of sampling be modified to April 10, 1401.

Acronym

IRCT registration information

IRCT registration number: **IRCT20131009014957N11**
Registration date: **2021-02-11, 1399/11/23**
Registration timing: **prospective**

Last update: **2022-03-16, 1400/12/25**
Update count: **1**

Registration date

2021-02-11, 1399/11/23

Registrant information

Name

Azizeh Farshbaf-khalili

Name of organization / entity

Tabriz university of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 41 1333 9151

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-08, 1401/01/19

Expected recruitment end date

2022-10-11, 1401/07/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of supplementation with selenium-enriched saccharomyces cervisiae yeast on sperm parameters, serum levels of androgens, sexual function, and quality of sexual life in oligoasthenoteratozoosperm infertile men: A triple-blind randomized controlled clinical trial

Public title

The effect of supplementation with organic selenium on sperm parameters, serum levels of androgens, sexual function, and quality of sexual life in infertile men

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

An infertile married man with idiopathic oligoasthenoteratozoosperm for at least one year Age 20 to 40 years No problem in wife fertility Non-addiction to alcohol and substance abuse

Exclusion criteria:

Azospermia Infectious disease and anatomical abnormalities of the genital tract Varicocele-related infertility History of pelvic surgeries or need to do so Cancer, liver and gallbladder diseases, diabetes, thyroid disorders, kidney failure, uncontrolled blood pressure, cerebral hemorrhage, retinal hemorrhage, unilateral testicular atrophy Abnormal karyotype History of receiving chemotherapy drugs, corticosteroids, anticoagulants, testosterone, anti-androgens Taking any chemical or herbal medicine specific to infertility during the project and the previous three months BMI>=30

Age

From **20 years** old to **45 years** old

Gender

Male

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Eligible individuals will be assigned into two groups of selenium-enriched yeast supplements or placebo using a randomized blocking method with the 4 and 6 sized blocks and 1: 1 allocation ratio. The allocation sequence will be generated by the researcher through RAS (Random Allocation Software). The medicines and placebo will be placed in a Flacons. Falcons will be assigned numbers from 1 to 80. They will be the same shaped, closed, opaque, and contain 90 capsules, and their preparation will be done based on the sequence allocation by the person not involved in the research.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The first group will receive one 250 mg capsule of selenium-enriched yeast (containing 200 micrograms of selenium) daily, and the second group will receive a placebo capsule (containing 250 mg of yeast) that will be the same shape, color, and weight. Participants, the principal investigator, health care personnel, those evaluating the outcome, the Data Safety and Monitoring Committee, and those drafting the article will be blinded.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of TabrizUniversity of Medical Sciences

Street address

. Vice Chancellor for Research and Technology,Golgasht St

City

Tabriz

Province

East Azarbaijan

Postal code

5165665931

Approval date
2020-11-23, 1399/09/03
Ethics committee reference number
IR.TBZMED.REC.1399.805

Health conditions studied

1

Description of health condition studied
Oligoasthenoteratozoospermia
ICD-10 code
N46
ICD-10 code description
Male infertility

Primary outcomes

1

Description
Semen parameters (number, morphology, motility)
Timepoint
Baseline and 12 weeks after the intervention
Method of measurement
To calculate the number of live sperm, morphology and motility, a light microscope with a magnification of 1000× will be used.

2

Description
Serum levels of androgens (total testosterone, free testosterone and dehydroepiandrosterone
Timepoint
Baseline and 12 weeks after the intervention
Method of measurement
Using ELISA method by monobind kits

3

Description
Sexual function score
Timepoint
Baseline and 12 weeks after the intervention
Method of measurement
BSFI: Brief Sexual Function Inventory

4

Description
Sex quality of life score
Timepoint
Baseline and 12 weeks after the intervention
Method of measurement
Sexual Quality of Life-M: SQOL-M

Secondary outcomes

1

Description
Pregnancy rate
Timepoint
12 weeks after the intervention
Method of measurement
Follow-up for up to two months after the intervention and quantitative Beta-hCG testing if necessary

2

Description
Side effects
Timepoint
During and after the intervention
Method of measurement
Questionnaire

3

Description
Satisfaction with medication
Timepoint
During and after the intervention
Method of measurement
Satisfaction rate questionnaire

Intervention groups

1

Description
Intervention group: They will take one 250 mg S.cerevisiae yeast capsule containing 200 micrograms of organic selenium daily orally with meals for 3 months. Organic selenium will be produced at the Nutrition Research Center.
Category
Treatment - Drugs

2

Description
Control group: One 250 mg oral capsule containing S. cerevisiae yeast daily for 3 months, which will be similar in shape, color, and weight to selenium-containing capsules and will be produced at the Nutrition Research Center.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Nutrition Research Center
Full name of responsible person
Azizeh Farshbaf-Khalili
Street address
Nutrition Research Center, Tabriz University of Medical Sciences; Attar Neishabouri avenue, Golgasht
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Mohammad Samiei
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Central building of Tabriz University of Medical Sciences., Azadi St., Golgasht St
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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
Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
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Position
Assistant Professor
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Person responsible for updating data

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Azizeh Farshbaf-khalili
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Assistant Profeassor
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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is 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

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

Data on the main outcome will be published

When the data will become available and for how long

Six months after printing the results

To whom data/document is available

Researchers at institutions have access to data

Under which criteria data/document could be used

In order to help scientific progress in the field of research

From where data/document is obtainable

farshbafa@tbzmed.ac.ir

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

Scientific approval of the applicant by Tabriz University of Medical Sciences

Comments