

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jul 2026

### Effects of simultaneous supplementation of vitamin E and omega-3 fatty acids on semen parameters of workers exposed to physical stressors

#### Protocol summary

Registration timing: **prospective**

#### Study aim

Effects of simultaneous supplementation of vitamin E and omega-3 fatty acids on semen parameters of workers exposed to physical stressors

Last update: **2021-02-09, 1399/11/21**

Update count: **0**

#### Registration date

2021-02-09, 1399/11/21

#### Design

These individuals are divided into four groups according to the randomized double-blind blocking method, the first group will receive vitamin E and the second group omega-3 fatty acids, the third group will receive vitamin E and omega-3 fatty acids together, and the fourth group will receive placebo as a control group.

#### Registrant information

##### Name

Somayeh Farhang Dehghan

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2243 2040

##### Email address

somayeh.farhang@gmail.com

#### Settings and conduct

Semen and blood samples are taken before and after the intervention

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Participants/Inclusion and exclusion criteria

Male, married, age group 20-40 years, more than one year of work experience, no alcohol consumption, no smoking, no use of special drugs and antioxidants such as selenium and vitamins B, E and C, no use of bodybuilding supplements No history of infertility in family history, no organic diseases affecting sexual function (diabetes, kidney disease, angina, heart failure and arterial hypertension, pituitary gland disease and chronic obstructive pulmonary disease), no swelling and testicular infection, No history of varicocele, no history of radiation therapy and chemotherapy

#### Expected recruitment start date

2021-03-21, 1400/01/01

#### Expected recruitment end date

2021-06-22, 1400/04/01

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Intervention groups

Workers exposed to physical stressors

#### Scientific title

Effects of simultaneous supplementation of vitamin E and omega-3 fatty acids on semen parameters of workers exposed to physical stressors

#### Main outcome variables

Semen parameters Blood testosterone levels Blood LH levels Blood FSH levels

#### Public title

Effect of vitamin E and omega-3 fatty acids on semen parameters

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210207050290N1**

Registration date: **2021-02-09, 1399/11/21**

## Purpose

Prevention

## Inclusion/Exclusion criteria

### Inclusion criteria:

Male gender, age group 40-40 years, more than one year of work experience, no alcohol consumption, no smoking, no use of special drugs and antioxidants such as selenium and vitamins B, E and C, no use of bodybuilding supplements, no History of infertility in family history, lack of organic diseases affecting sexual function (diabetes, kidney disease, angina, heart failure and arterial hypertension, pituitary gland disease and chronic obstructive pulmonary disease), no swelling and testicular infection, no history Varicocele disease, no history of radiation therapy and chemotherapy, no use of laptop on the legs when working with it, no prolonged sitting and very high physiological activity and a score of 22 or lower in the General Health Questionnaire (GHQ), which shows The giver is the health of the person.

### Exclusion criteria:

## Age

From **20 years** old to **40 years** old

## Gender

Male

## Phase

3

## Groups that have been masked

- Participant
- Investigator

## Sample size

Target sample size: **92**

## Randomization (investigator's opinion)

Randomized

## Randomization description

The sample size for each group was 23 people, a total of 92 people (23 4 4). These individuals are divided into four groups according to the randomized double-blind blocking method, the first group will receive vitamin E and the second group omega-3 fatty acids, the third group will receive vitamin E and omega-3 fatty acids together, and the fourth group will receive placebo as a control group. Appeared. The blocking method is usually used to balance the number of samples assigned to each of the studied groups and the number of samples assigned to each of the studied groups is equal. Conventional websites will be used to generate a random sequence. In the double-blind method, the participants studied and the project executive partner did not know the contents of the supplement can.

## Blinding (investigator's opinion)

Double blinded

## Blinding description

The participant and the researcher (in relation to the participant) do not know any of the contents of the can. The contents of the can have been prepared and coded by the executor.

## Placebo

Used

## Assignment

Factorial

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

School of Public Health & Neuroscience Research Center, Shahid Beheshti University of Medical Scie

##### Street address

Daneshjoo Blvd, Velenjak, Shahid Chamran Highway

##### City

Tehran

##### Province

Tehran

##### Postal code

1983535511

#### Approval date

2020-12-22, 1399/10/02

#### Ethics committee reference number

IR.SBMU.PHNS.REC.1399.157

## Health conditions studied

### 1

#### Description of health condition studied

Workers exposed to physical stressors

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Properties of semen - blood testosterone, LH and FSH

#### Timepoint

Before and after the intervention

#### Method of measurement

WHO Instruction - ELISA Kit

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Workers exposed to physical stressors

#### Category

N/A

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**  
Sarem Hospital  
**Full name of responsible person**  
Mr. Younesi  
**Street address**  
Ekbatan Town - End of Phase 3.  
**City**  
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**Postal code**  
1396956111  
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somayeh.farhang@gmail.com

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**  
Shahid Beheshti University of Medical Sciences  
**Full name of responsible person**  
Somayeh Farhang  
**Street address**  
, Daneshjoo Blvd, Velenjak, Shahid Chamran Highway  
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somayeh.farhang@gmail.com  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Shahid Beheshti 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**  
Shahid Beheshti University of Medical Sciences  
**Full name of responsible person**  
Somayeh Farhang  
**Position**  
Assistant Professor  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Occupational Health  
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## Person responsible for scientific inquiries

### Contact

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Assistant Professor  
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## Person responsible for updating data

### Contact

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Shahid Beheshti University of Medical Sciences  
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**Position**  
Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Occupational Health

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**Postal code**

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**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**

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