Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

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

Protocol summary

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

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.

Settings and conduct
Semen and blood samples are taken before and after the intervention

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

Intervention groups
Workers exposed to physical stressors

Main outcome variables
Semen parameters Blood testosterone levels Blood LH levels Blood FSH levels

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210207050290N1**
Registration date: **2021-02-09, 1399/11/21**
Registration timing: **prospective**

Last update: **2021-02-09, 1399/11/21**
Update count: **0**

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

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

Recruitment status
Recruitment complete

Funding source

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

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

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

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
Tehran
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Postal code
1396956111
Phone
+98 21 4467 0886
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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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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
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Other areas of specialty/work
Occupational Health
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Person responsible for scientific inquiries

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Person responsible for updating data

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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