

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of Extremely Low Frequency Electromagnetic Fields Effects on Oxidative Stress and Reducing the effects of Oxidative Stress by Intervention of Vitamin E and C in Shaheed Bastami Power Plant's Workers; A Duple Blind, Randomized Clinical Trial Study

Protocol summary

Study aim

The aim of this study will be to determine the effect of exposure to Extremely Low-Frequency Electromagnetic Fields (ELF-EMFs) on oxidative stress and also the feasibility of using vitamins E and C as a therapeutic solution in order to reduce the effects of oxidative stress.

Design

A controlled, double-blinded, permuted block randomization clinical trial among 96 power plant workers for 3 months.

Settings and conduct

The workers who are working in the different sections of the power plant will be divided into four groups, and group 1 will receive 400 IU vitamin E, group 2 will receive 1000 mg vitamin C, group C will receive 400 IU vitamin E and 1000 mg vitamin C, and group 4 will not receive any intervention. The data collectors will be blinded through coded participants.

Participants/Inclusion and exclusion criteria

Inclusion criteria: in the range of 20 to 50 years of age, working full time at the power plant and at least one year of experience at the power plant. Exclusion criteria: renal disorders, hypertension and using drugs and dietary supplementary with antioxidant properties.

Intervention groups

Group 1: 400 IU vitamin E; Group 2: 1000 mg vitamin C; Group 3: 400 IU vitamin E and 1000 mg vitamin C; Group 4: the control group does not receive the intervention.

Main outcome variables

Malondialdehyde; Superoxide dismutase; Catalase; Glutathione; Ceruloplasmin; Total Antioxidant Capacity; DNA damage; apoptosis; Interleukin 6; Interleukin 1b; Tumor necrosis factor alpha; The level of extremely low frequency electromagnetic fields exposure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT2016020926466N1**

Registration date: **2017-02-28, 1395/12/10**

Registration timing: **prospective**

Last update: **2018-12-12, 1397/09/21**

Update count: **1**

Registration date

2017-02-28, 1395/12/10

Registrant information

Name

Majid Bagheri Hossein Abadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 23 3236 1718

Email address

m.bagheri@shmu.ac.ir

Recruitment status

Recruitment complete

Funding source

The study has founded by Shahroud university of Medical Sciences

Expected recruitment start date

2017-06-04, 1396/03/14

Expected recruitment end date

2017-10-21, 1396/07/29

Actual recruitment start date

empty

Actual recruitment end date

empty
Trial completion date
empty

Scientific title
Evaluation of Extremely Low Frequency Electromagnetic Fields Effects on Oxidative Stress and Reducing the effects of Oxidative Stress by Intervention of Vitamin E and C in Shaheed Bastami Power Plant's Workers; A Double Blind, Randomized Clinical Trial Study

Public title
Effects of using vitamins E and C in reducing Extremely Low-Frequency Electromagnetic Fields adverse health effects

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
At least one year of experience at the power plant
Working full time at the power plant In the range of 20 to 50 years of age

Exclusion criteria:
Hypertension according to WHO's definition
Using antioxidant dietary supplements
Using drugs with antioxidant properties
Using vitamins and antioxidants, such as vitamin E, C and beta-carotene and selenium

Age
From **20 years** old to **50 years** old

Gender
Male

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **95**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization assignment will be done by permuted blocked method into four groups using computer-generated random numbers. The allocation will be concealed from participants.

Blinding (investigator's opinion)
Double blinded

Blinding description
The study will be double-blind. Data analyzer, participants, and outcome assessor won't be informed of allocation

Placebo
Used

Assignment
Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahrood University of Medical Sciences

Street address

Hafte-Tir square, Shahrood University of Medical Sciences

City

Shahrood

Province

Semnan

Postal code

3614773955

Approval date

2016-09-10, 1395/06/20

Ethics committee reference number

IR.SHMU.1395.94

Health conditions studied

1

Description of health condition studied

Oxidative stress, DNA damage, Apoptosis, Pre-inflammatory cytokines

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Serum level of malondialdehyde

Timepoint

Before and after intervention

Method of measurement

Enzyme-linked immunosorbent assay (ELISA)

2

Description

Serum level of superoxide dismutase

Timepoint

Before and after intervention

Method of measurement

Enzyme-linked immunosorbent assay (ELISA)

3

Description

Serum level of catalase

Timepoint

Before and after intervention

Method of measurement

Enzyme-linked immunosorbent assay (ELISA)

4**Description**

Serum level of glutathione

Timepoint

Before and after intervention

Method of measurement

Enzyme-linked immunosorbent assay (ELISA)

5**Description**

Serum level of ceruloplasmin

Timepoint

Before and after intervention

Method of measurement

Enzyme-linked immunosorbent assay (ELISA)

6**Description**

Serum level of total antioxidant capacity

Timepoint

Before and after intervention

Method of measurement

Enzyme-linked immunosorbent assay (ELISA)

7**Description**

DNA damage index

Timepoint

Before and after intervention

Method of measurement

Comet Assay

8**Description**

Apoptosis

Timepoint

Before and after intervention

Method of measurement

Flow cytometry

9**Description**

Serum level of interleukin 6

Timepoint

Before and after intervention

Method of measurement

Enzyme-linked immunosorbent assay (ELISA)

10**Description**

Serum level of interleukin-1 beta

Timepoint

Before and after intervention

Method of measurement

Enzyme-linked immunosorbent assay (ELISA)

11**Description**

Serum level of tumor necrosis factor alpha

Timepoint

Before and after intervention

Method of measurement

Enzyme-linked immunosorbent assay (ELISA)

Secondary outcomes**1****Description**

Cholesterol

Timepoint

Before and after intervention

Method of measurement

Enzymatic-colorimetric at 546 nm wavelength

2**Description**

Complete blood count

Timepoint

Before and after intervention

Method of measurement

By Cell Counter

3**Description**

High-density lipoprotein

Timepoint

Before and after intervention

Method of measurement

Immuno-inhibition

4**Description**

Low-density lipoprotein

Timepoint

Before and after intervention

Method of measurement

Direct method

5**Description**

Alanine transaminase

Timepoint

Before and after intervention

Method of measurement

Colorimetric at 570 nm wavelength

6**Description**

Aspartate transaminase

Timepoint

Before and after intervention
Method of measurement
Colorimetric at 340 nm wavelength

7

Description
Creatinine
Timepoint
Before and after intervention
Method of measurement
Jaffe

8

Description
Urea
Timepoint
Before and after intervention
Method of measurement
UV test

9

Description
Uric acid
Timepoint
Before and after intervention
Method of measurement
Enzymatic-colorimetric at 520 nm wavelength

10

Description
Triglycerides
Timepoint
Before and after intervention
Method of measurement
Enzymatic-colorimetric at 510 nm wavelength

11

Description
Glucose
Timepoint
Before and after intervention
Method of measurement
Enzymatic-colorimetric at 546 nm wavelength

12

Description
Total protein
Timepoint
Before and after intervention
Method of measurement
Biuret

13

Description
Albumin
Timepoint
Before and after intervention

Method of measurement
Bromocresol green

14

Description
Vitamin D
Timepoint
Before and after intervention
Method of measurement
Enzyme-linked immunosorbent assay (ELISA)

15

Description
Calcium
Timepoint
Before and after intervention
Method of measurement
Arsenzoza

16

Description
Phosphorous
Timepoint
Before and after intervention
Method of measurement
U.V test

17

Description
High sensitivity C-reactive protein
Timepoint
Before and after intervention
Method of measurement
Immunoturb

Intervention groups

1

Description
Vitamin E, 400 IU oral tablet, once a day for three months
Category
Prevention

2

Description
Vitamin C, 1000 mg oral tablet, once a day for three months
Category
Prevention

3

Description
Vitamins E and C, 400 IU and 1000 mg oral tablet, once a day for three months
Category

Prevention

4

Description

There will be no intervention

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahroud University of Medical Sciences

Full name of responsible person

Majid Bagheri Hossein Abadi and Pirasteh Norouzi

Street address

Hafte-Tir Square, Shahroud University of Medical Sciences

City

Shahroud

Province

Semnan

Postal code

3617753917

Phone

+98 23 3236 4499

Email

m.bagheri@shmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahroud University of Medical Sciences

Full name of responsible person

Mohammad Hassan Emamian

Street address

Hafte-Tir Square, Shahroud University of Medical Sciences

City

Shahroud

Province

Semnan

Postal code

3617753917

Phone

+98 23 3239 5054

Email

emamian@shmu.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahroud 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

Shahroud University of Medical Sciences

Full name of responsible person

Majid Bagheri Hossein Abadi

Position

Consultant

Latest degree

Master

Other areas of specialty/work

Occupational Health

Street address

Hafte-Tir square, Shahroud University of Medical Sciences

City

Shahroud

Province

Semnan

Postal code

3614773955

Phone

+98 23 3236 1718

Fax

Email

m.bagheri@shmu.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahroud University of Medical Sciences

Full name of responsible person

Mehdi Mirzaii

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Bacteriology

Street address

Hafte-Tir Square, Shahroud University of Medical Sciences

City

Shahroud

Province

Semnan

Postal code

3617753917

Phone

+98 23 3236 4499

Fax

Email

mirzaii1386@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Shahroud University of Medical Sciences

Full name of responsible person

Majid Bagheri Hossein Abadi

Position

Consultant

Latest degree

Master

Other areas of specialty/work

Occupational Health

Street address

Shahroud University of Medical Sciences, Hafte tir
Square

City

Shahroud

Province

Semnan

Postal code

3614773955

Phone

+98 23 3236 1718

Fax

Email

m.bagheri@shmu.ac.ir

Web page address

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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Oxidative stress, DNA damage, Apoptosis, and pro-inflammatory cytokines

When the data will become available and for how long

After publishing the article

To whom data/document is available

Scientific researchers

Under which criteria data/document could be used

Without any condition

From where data/document is obtainable

Vice Chancellor for Research, Shahroud University of medical sciences

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

By sending a request email

Comments