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 Duble 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 Duble 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 Shahroud University of Medical Sciences

Street address

Hafte-Tir square, Shahrood University of Medical Sciences

City

Shahroud

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
Immunoinhibition

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

Arsenoza

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
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Shahroud
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3617753917
Phone
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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
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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
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Person responsible for scientific inquiries

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Full name of responsible person
Mehdi Mirzaii
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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Majid Bagheri Hossein Abadi

Position

Consultant

Latest degree

Master

Other areas of specialty/work

Occupational Health

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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