

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Sep 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 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**

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**  
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

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###### Province

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**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  
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**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**