

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jul 2026

### The study of the protective effect efficiency of antioxidant CoQ10 supplement on blood levels of total antioxidant capacity, antioxidant enzymes activity and malondialdehyde of workers in ceramic and printing industries

#### Protocol summary

2016-06-25, 1395/04/05

##### Summary

The study aimed to determine the protective effect of antioxidant CoQ10 supplement on blood levels of oxidative stress bio markers induced by occupational exposure to lead and cadmium metals and organic solvents such as toluene and xylene among workers in ceramic and printing industries. Randomized, double-blind, placebo-controlled crossover trial was selected as a study design. Totally, 40 of the printing industry workers and 40 workers tile industry are consented to participate in the study and having no history of chronic disease, randomly divided into 4 groups. The intervention group consisted of 20 workers who receive capsules 60 mg oral COQ10 twice daily for 60 days and the control group consisted of 20 patients who receive placebo in the same amount. The study includes two intervention phases and one washout period phase. The duration of the intervention phases and washout period phase is two months and one month, respectively and the duration of study will last five months. At the end of the study, the reduction level of oxidative stress will be evaluated by comparing the bio markers level before and after the intervention.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016061228407N1**

Registration date: **2016-06-25, 1395/04/05**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

##### Registrant information

###### Name

Maryam Hormozi

###### Name of organization / entity

Zahedan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 54 3348 8718

###### Email address

dr.hormozi@zaums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Zahedan University of Medical Sciences

##### Expected recruitment start date

2016-07-10, 1395/04/20

##### Expected recruitment end date

2016-12-10, 1395/09/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The study of the protective effect efficiency of antioxidant CoQ10 supplement on blood levels of total antioxidant capacity, antioxidant enzymes activity and malondialdehyde of workers in ceramic and printing industries

##### Public title

The effectiveness of CoQ10 antioxidant supplements in

the prevention of the harmful effects of occupational exposure to heavy metals and organic solvents

#### **Purpose**

Prevention

#### **Inclusion/Exclusion criteria**

Inclusion criteria: Having at least one year of experience in the production line; giving consent to participate in the study  
Exclusion criteria: History of chronic diseases of the thyroid, liver, kidney, diabetes, cardiovascular disease, cancer and high blood pressure; use of antioxidant supplements by person; Having Positive test G6PDH

#### **Age**

No age limit

#### **Gender**

Both

#### **Phase**

N/A

#### **Groups that have been masked**

No information

#### **Sample size**

Target sample size: 80

#### **Randomization (investigator's opinion)**

Randomized

#### **Randomization description**

#### **Blinding (investigator's opinion)**

Double blinded

#### **Blinding description**

#### **Placebo**

Used

#### **Assignment**

Crossover

#### **Other design features**

### **Secondary Ids**

empty

### **Ethics committees**

#### **1**

##### **Ethics committee**

###### **Name of ethics committee**

Zahedan University of Medical Sciences

###### **Street address**

Pardis of the University of Medical Sciences, Doctor Hsabi Squire

###### **City**

Zahedan

###### **Postal code**

009816743175

##### **Approval date**

2016-06-05, 1395/03/16

##### **Ethics committee reference number**

ir.zaums.rec.1395.85

### **Health conditions studied**

#### **1**

##### **Description of health condition studied**

Toxic effect of organic solvents

##### **ICD-10 code**

T52.2

##### **ICD-10 code description**

Homologues of benzene

#### **2**

##### **Description of health condition studied**

Toxic effect of metals

##### **ICD-10 code**

T56.0

##### **ICD-10 code description**

Lead and its compounds

#### **3**

##### **Description of health condition studied**

Toxic effect of metals

##### **ICD-10 code**

T56.3

##### **ICD-10 code description**

Cadmium and its compounds

### **Primary outcomes**

#### **1**

##### **Description**

malondialdehyde

##### **Timepoint**

Before the intervention, two months after the intervention.

##### **Method of measurement**

Measurement of blood plasma levels of malondialdehyde in terms of nmol per ml

#### **2**

##### **Description**

total antioxidant capacity

##### **Timepoint**

total antioxidant capacity

##### **Method of measurement**

Measurement of antioxidant capacity in blood plasma in terms of micromoles per liter

#### **3**

##### **Description**

Superoxide dismutase activity

##### **Timepoint**

Before the intervention, two months after the intervention

##### **Method of measurement**

Measurement of the level of erythrocyte superoxide dismutase activity in terms of unit per gram of hemoglobin

## 4

### **Description**

Glutathione peroxidase activity

### **Timepoint**

Before the intervention, two months after the intervention.

### **Method of measurement**

Measurement of the level of erythrocyte glutathione peroxidase activity in terms of unit per gram of hemoglobin

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### **Description**

Catalase activity

### **Timepoint**

Before the intervention, two months after the intervention

### **Method of measurement**

Measurement of the level of erythrocyte catalase activity in terms of unit per gram of hemoglobin

## **Secondary outcomes**

## 1

### **Description**

Headache

### **Timepoint**

Before the intervention and at the end of intervention

### **Method of measurement**

According to Commenting person

## 2

### **Description**

Nausea

### **Timepoint**

Before the intervention and at the end of intervention

### **Method of measurement**

According to Commenting person

## **Intervention groups**

## 1

### **Description**

The intervention group consists of 20 workers exposed to organic solvents in the printing industry and 20 workers exposed to heavy metals in the tile industry who received capsules 60 mg oral COQ10 twice daily for 60 days.

### **Category**

Placebo

## 2

### **Description**

The control group consists of 20 workers exposed to organic solvents in the printing industry and 20 workers exposed to heavy metals in the tile industry who received capsules 60 mg oral placebo twice daily for 60

days.

### **Category**

Placebo

## **Recruitment centers**

## 1

### **Recruitment center**

#### **Name of recruitment center**

Tile Industry of Niloofar

#### **Full name of responsible person**

Maryam Hormozi, Student of ph.D  
by.research(Occupational Health)

#### **Street address**

Industrial Town, Niloofar Ceramics Industry

#### **City**

Birjand

## 2

### **Recruitment center**

#### **Name of recruitment center**

Printing Industry of Golru

#### **Full name of responsible person**

Maryam Hormozi, Student of ph.D  
by.research(Occupational Health)

#### **Street address**

Next to SAIPA, Persian Gulf Boulevard

#### **City**

Birjand

## **Sponsors / Funding sources**

## 1

### **Sponsor**

#### **Name of organization / entity**

Zahedan University of Medical Sciences

#### **Full name of responsible person**

Mohsen Taheri (Director of Research)

#### **Street address**

Doctor Hesabi Squar

#### **City**

Zahedan

### **Grant name**

### **Grant code / Reference number**

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

Yes

### **Title of funding source**

Zahedan University of Medical Sciences

### **Proportion provided by this source**

100

### **Public or private sector**

*empty*

### **Domestic or foreign origin**

*empty*

### **Category of foreign source of funding**

*empty*

### **Country of origin**

### **Type of organization providing the funding**

empty

## Person responsible for general inquiries

### Contact

**Name of organization / entity**

Zahedan University of Medical Sciences

**Full name of responsible person**

Maryam Hormozi

**Position**

Faculty Member, Student of ph.D  
by.research(Occupational Health)

**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

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Zahedan University of Medical Sciences

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Faculty Member

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## Person responsible for scientific inquiries

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**Other areas of specialty/work**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

empty

**Study Protocol**

empty

**Statistical Analysis Plan**

empty

**Informed Consent Form**

empty

**Clinical Study Report**

empty

**Analytic Code**

empty

**Data Dictionary**

empty