

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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

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

2016-06-25, 1395/04/05

Registrant information

Name

Maryam Hormozi

Name of organization / entity

Zahedan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Email address

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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

Measurment 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

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

5

Description

Catalase activity

Timepoint

Before the intervention, two months after the intervention

Method of measurement

Measurment 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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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