Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effect of coenzyme Q10 supplementation on oxidative stress, inflammation, hematology, liver and kidney profiles in organophosphate poisoned patients: a single-blind randomized clinical trial

Protocol summary

Study aim
To assess the effect of coenzyme Q10 supplementation on oxidative stress, inflammation, hematology, liver and kidney profiles in organophosphate poisoned patients

Design
This is a Phase III single-blind randomized clinical trial with a control group with parallel groups, in which 40 eligible patients will be randomly assigned to the intervention and control groups using drawing of lots.

Settings and conduct
This study will be conducted at the Sina Hospital in Hamadan city, involving 40 eligible organophosphate poisoned patients. The patients will be randomly assigned to the intervention and control groups through the drawing of lots. This trial will be single-blinded.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age of 20 to 40 years, Poisoned with organophosphate Exclusion criteria: Swallowing disorders

Intervention groups
Intervention group: Routine treatment for organophosphate poisoning plus one coenzyme Q10 supplement, 100 mg twice daily, for one week Control Group: Routine treatment for organophosphate poisoning plus one placebo capsule (starch) twice daily for one week

Main outcome variables
Primary outcome: Lipid peroxidation level; Total blood antioxidant capacity; Blood thiol group levels; Catalase enzyme activity; CRP level; ESR level; WBC level; RBC level; Hemoglobin level; Triglyceride level; LDL level; HDL level; Urea level; Creatinine level; Albumin level; Protein level

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120215009014N610**
Registration date: **2026-05-15, 1405/02/25**
Registration timing: **prospective**

Last update: **2026-05-15, 1405/02/25**
Update count: **0**

Registration date
2026-05-15, 1405/02/25

Registrant information
Name
Jalal Poorolajal
Name of organization / entity
Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences
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Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-05-31, 1405/03/10

Expected recruitment end date
2028-05-19, 1407/02/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Effect of coenzyme Q10 supplementation on oxidative stress, inflammation, hematology, liver and kidney profiles in organophosphate poisoned patients: a single-blind randomized clinical trial

Public title
Effect of coenzyme Q10 supplementation on oxidative stress, inflammation, hematology, liver and kidney profiles in organophosphate poisoned patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age of 20 to 40 years, Poisoned with organophosphate
Exclusion criteria:
Swallowing disorders
Age
From **20 years** old to **40 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant

Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Random allocation of patients to intervention and control groups by lottery. For this purpose, we prepare two sheets, write "intervention" on one and "control" on the other. Then, with each patient's visit, one of the sheets is randomly taken and the patient is assigned to the intervention or control group.
Blinding (investigator's opinion)
Single blinded
Blinding description
Both the medications and placebos will have the same shape. Consequently, patients will remain unaware of the type of intervention they receive. Therefore, the trial will be conducted as a single-blind study.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Hamadan University of Medical Sciences
Street address
Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences, Fahmideh Avev
City
Hamadan
Province
Hamadan
Postal code
6517838695
Approval date
2026-05-09, 1405/02/19
Ethics committee reference number
IR.UMSHA.REC.1405.113

Health conditions studied

1

Description of health condition studied
Organophosphate poisening
ICD-10 code
T60.0
ICD-10 code description
Toxic effect of organophosphate and carbamate insecticides

Primary outcomes

1

Description
Lipid peroxidation level
Timepoint
Before the intervention and one week after the intervention
Method of measurement
Using TBA reagent at a wavelength of 532 nm by a spectrophotometer

2

Description
Total blood antioxidant capacity
Timepoint
Before the intervention and one week after the intervention
Method of measurement
Using TPTZ reagent at a wavelength of 593 nm by a spectrophotometer

3

Description
Blood thiol group levels
Timepoint
Before the intervention and one week after the intervention
Method of measurement
Using DTNB reagent at a wavelength of 412 nm by a spectrophotometer

4

Description
Catalase enzyme activity
Timepoint
Before the intervention and one week after the intervention
Method of measurement
Using H_2O_2 reagent and sodium phosphate buffer at a wavelength of 240 nm by a spectrophotometer

5

Description
CRP level
Timepoint
Before the intervention and one week after the intervention
Method of measurement
By collecting and testing a blood sample

6

Description
ESR level
Timepoint
Before the intervention and one week after the intervention
Method of measurement
By collecting and testing a blood sample

7

Description
WBC level
Timepoint
Before the intervention and one week after the intervention
Method of measurement
By collecting and testing a blood sample

8

Description
RBC level
Timepoint
Before the intervention and one week after the intervention
Method of measurement
By collecting and testing a blood sample

9

Description
Hemoglobin level
Timepoint
Before the intervention and one week after the intervention
Method of measurement
By collecting and testing a blood sample

10

Description
Triglyceride level
Timepoint
Before the intervention and one week after the intervention
Method of measurement
By collecting and testing a blood sample

11

Description
LDL level
Timepoint
Before the intervention and one week after the intervention
Method of measurement
By collecting and testing a blood sample

12

Description
HDL level
Timepoint
Before the intervention and one week after the intervention
Method of measurement
By collecting and testing a blood sample

13

Description
Urea level
Timepoint
Before the intervention and one week after the intervention
Method of measurement
By collecting and testing a blood sample

14

Description
Creatinine level
Timepoint
Before the intervention and one week after the intervention
Method of measurement
By collecting and testing a blood sample

15

Description
Albumin level
Timepoint
Before the intervention and one week after the intervention
Method of measurement
By collecting and testing a blood sample

16

Description
Protein level
Timepoint
Before the intervention and one week after the

intervention

Method of measurement

By collecting and testing a blood sample

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Routine treatment for organophosphate poisoning plus one coenzyme Q10 supplement, 100 mg twice daily, for one week

Category

Treatment - Drugs

2

Description

Control Group: Routine treatment for organophosphate poisoning plus one placebo capsule (starch) twice daily for one week

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina Hospital in Hamadan city

Full name of responsible person

Dr Freshteh Mehri

Street address

School of Medicine, Hamadan University of Medical Sciences, Fahmideh Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Dr Freshteh Mehri

Position

Toxicologist

Latest degree

Ph.D.

Other areas of specialty/work

Toxicology

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Person responsible for scientific inquiries

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Latest degree
Ph.D.

Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available