

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Evaluation the efficiency of coenzyme Q10 (ubiquinone) supplementation on cisplatin-induced nephrotoxicity inpatients under chemotherapy

#### Protocol summary

##### Study aim

Determining the effect of coenzyme Q10 supplementation on cisplatin induced nephrotoxicity in patients undergoing chemotherapy

##### Design

A clinical trial with a control group with a parallel, double-blind, randomized phase 3 group is performed on 46 patients.

##### Settings and conduct

In this study, cancer patients referred to Hajar Hospital who receive cisplatin at a dose of 50 to 75 mg / m<sup>2</sup> will be examined under the supervision of an adult hematologist and oncologist. Cancer patients will then be randomly divided into control and intervention groups. Patients will receive ubiquinone 30 mg daily. The duration of medication will be 8 weeks after the first dose. The control group will also receive placebo in cans of the same shape and drugs of the same color (maltodextrin).

##### Participants/Inclusion and exclusion criteria

Inclusion criteria 1- Age between 18-75 years, 2- Do not take antioxidant and anti-inflammatory supplements for at least 1 month before the start of the study. 3- Willingness to cooperate in the research project and completing the informed consent form Exclusion criteria 1- Changing the method of drug treatment and taking antioxidant and anti-inflammatory supplements during the study period 2- Changing lifestyle

##### Intervention groups

In this study, cancer patients referred to Hajar Hospital who receive cisplatin at a dose of 50 to 75 mg / m<sup>2</sup> will be randomly divided into control and intervention groups. Patients will receive ubiquinone 30 mg daily. The duration of medication will be 8 weeks after the first dose. The control group will also receive placebo in cans of the same shape and drugs of the same color (maltodextrin).

##### Main outcome variables

(BUN) Blood urea nitrogen ,(GFR) Glomerular filtration

rate, Serum creatinine

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20211205053287N1**

Registration date: **2022-04-28, 1401/02/08**

Registration timing: **registered\_while\_recruiting**

Last update: **2022-04-28, 1401/02/08**

Update count: **0**

##### Registration date

2022-04-28, 1401/02/08

##### Registrant information

##### Name

Mehrdad Sepehrnia

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 38 3222 0016

##### Email address

dr.sepehrnia2008@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-04-21, 1401/02/01

##### Expected recruitment end date

2022-06-22, 1401/04/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

Evaluation the efficiency of coenzyme Q10 (ubiquinone) supplementation on cisplatin-induced nephrotoxicity inpatients under chemotherapy

### Public title

Evaluation the efficiency of coenzyme Q10 (ubiquinone) supplementation on cisplatin-induced nephrotoxicity

### Purpose

Supportive

### Inclusion/Exclusion criteria

#### Inclusion criteria:

1- Age between 80-20 years, 2- Do not take antioxidant and anti-inflammatory supplements for at least 1 month before the start of the study 3- Willingness to cooperate in the research project and completing the informed consent form Community Verified icon

#### Exclusion criteria:

1- Changing the method of drug treatment and taking antioxidant and anti-inflammatory supplements during the study period 2- Changing lifestyle (changing diet, physical activity and level of mental stress) during the study

### Age

From **20 years** old to **80 years** old

### Gender

Both

### Phase

3

### Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

### Sample size

Target sample size: **46**

### Randomization (investigator's opinion)

Randomized

### Randomization description

Patients are randomized using random allocation software. In the software, the number of groups and the number of samples and the type of groups are determined. Then the numbers 1 to 46 are randomly assigned to the control group and the intervention group. Intervention group: A Control group: B

### Blinding (investigator's opinion)

Double blinded

### Blinding description

In order for the patient and the intervening physician to remain blind in the intervention, all maltodextrin capsules are separated from the blister and the placebo is prepared in a series of pre-prepared medicine containers completely similar to the original drug form by the executor. The intervening physician and patients are kept blind to the type of drug (main or placebo) and the type of grouping A and B (which is the main group and which group is placebo).

### Placebo

Used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Shahrekord University of Medical Sciences

##### Street address

Chaharmahal and Bakhtiari - Shahrekord city - Kashani boulevard - Parstar street - Hajar hospital

##### City

Shahrekord

##### Province

Chahar-Mahal-va-Bakhtiari

##### Postal code

۸۸۱۵۷۱۳۴۷۱

#### Approval date

2021-09-28, 1400/07/06

#### Ethics committee reference number

IR.SKUMS.REC.1400.144

## Health conditions studied

### 1

#### Description of health condition studied

Nephrotoxicity due to cisplatin

#### ICD-10 code

N14.1

#### ICD-10 code description

Nephropathy induced by other drugs, medicaments and biological substances

## Primary outcomes

### 1

#### Description

Nephrotoxicity due to cisplatin

#### Timepoint

In patients receiving cisplatin, the tests are checked once before starting (Q10) supplementation and once after supplementation (2 months later).

#### Method of measurement

Check blood urea nitrogen (BUN) and creatinine (Cr) for patients

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: In 23 patients receiving cisplatin after checking the conditions for inclusion in the study, BUN, cr, GFR, Blood Group, Rh tests were checked and 60 Q10 tablets (produced by the drug treatment company) were given to them. Each tablet contains 30 mg of Q10 supplement and should be taken daily for 2 months. After the pills are completed, the patients' kidney function tests are checked again.

#### Category

Prevention

### 2

#### Description

Control group: 23 patients receiving cisplatin who will receive a placebo capsule containing 20 g of maltodextrin daily (produced by Amin Isfahan Pharmaceutical Company) for two months.

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Hajar Hospital, Shahrekord

##### Full name of responsible person

Parisa Javadian

##### Street address

Chaharmahal and Bakhtiari, Shahrekord city, Kashani boulevard, Parstar street, Hajar hospital

##### City

Shahrekord

##### Province

Chahar-Mahal-va-Bakhtiari

##### Postal code

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##### Phone

+98 38 3222 0016

##### Fax

+98 38 1333 4588

##### Email

info@skums.ac.ir

##### Web page address

<https://hajarhp.skums.ac.ir/>

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shahre-kord University of Medical Sciences

##### Full name of responsible person

Dr. Esfandiar Heydarian

#### Street address

Shahrekord, Hajar Hospital, second floor office building in front of accounting, Cancer Research Center

#### City

Shahrekord

#### Province

Chahar-Mahal-va-Bakhtiari

#### Postal code

۸۸۱۵۷۱۳۴۷۱

#### Phone

+98 38 3334 2414

#### Email

vcrt@skums.ac.ir

#### Web page address

<https://research.skums.ac.ir/>

#### Grant name

#### Grant code / Reference number

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

No

#### Title of funding source

Shahrekord 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

Shahre-kord University of Medical Sciences

##### Full name of responsible person

Dr.Mehrdad Sepehrnia

##### Position

Internal Medicine Resident

##### Latest degree

Medical doctor

##### Other areas of specialty/work

Internal Medicine

##### Street address

Kashan, Ayatollah Kashani St., Mullah Abdul Razzaq St., Kashi, in front of Ketabchi Conservatory, 13 Alley, Velayat, No. 24

##### City

kashan

##### Province

Isfahan

##### Postal code

8714654738

##### Phone

+98 31 5549 2237

##### Email

dr.sepehrnia2008@yahoo.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Shahre-kord University of Medical Sciences

**Full name of responsible person**

Dr.Mehrdad Sepehrnia

**Position**

Internal Medicine Resident

**Latest degree**

Medical doctor

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Shahre-kord University of Medical Sciences

**Full name of responsible person**

Dr.Mehrdad Sepehrnia

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## Sharing plan

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

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

There is no more information.

**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**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available