# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

09 Nov 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 / m2 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 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 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 / m2 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**
۸۸۱۵۷۱۳۴۷۱
**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**
Isfehan
**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

**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**
Isfehan

**Postal code**
8714654738

**Phone**
+98 31 5549 2237

**Email**
dr.sepehrnia2008@yahoo.com

## Person responsible for updating data

**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**
Isfehan

**Postal code**
8714654738

**Phone**
+98 31 5549 2237

**Email**
dr.sepehrnia2008@yahoo.com

## 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