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 / 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)

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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
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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
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Province
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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
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Kashan, Ayatollah Kashani St., Mullah Abdul Razzaq St., Kashi, in front of Ketabchi Conservatory, 13 Alley, Velayat, No. 24
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Person responsible for scientific inquiries

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Internal Medicine Resident

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Person responsible for updating data

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Position
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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