Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation the Effect of Curcumin Capsules on Prevention of Nephropathy Caused by Chemotherapy with Cisplatin(double blind clinical trial)

Protocol summary

Study aim
Determining the effect of nanocurcumin capsules on preventing kidney damage caused by chemotherapy with cisplatin

Design
A clinical trial with a control group, with parallel groups, double-blind, randomized, phase 3 will be conducted on 50 patients. random allocation software and A and B cards are used for randomization.

Settings and conduct
Cancer patients referred to Hajar Shehrkord Hospital, who were visited by the oncology specialist in 2022-2023, and if they are diagnosed with ovarian and head and neck cancer and are eligible, will be included in the study. Patients will be randomly assigned to intervention and control groups by random allocation method. This study will be conducted in a double-blind manner so that the patients and the researcher will not know the type of intervention

Participants/Inclusion and exclusion criteria
inclusion criteria: Cancer patients over 5 years of age who are being treated with cisplatin، Absence of kidney tumor، No kidney failure، be the same in terms of medications and supplements taken، exclusion criteria: non-cooperation of the patient، Having kidney stones،

Intervention groups
Intervention group: recipient of the standard chemotherapy drug cisplatin along with curcumin capsules in 9 weeks. Control group: recipient of the standard chemotherapy drug cisplatin along with placebo in 9 weeks (prepared and provided by Sina Curcumin Pharmaceutical Company).

Main outcome variables
Serum levels of sodium, potassium, calcium, magnesium, creatinine, BUN, quantitative GFR

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20221211056777N3**
Registration date: **2023-08-18, 1402/05/27**
Registration timing: **registered_while_recruiting**

Last update: **2023-08-18, 1402/05/27**
Update count: **0**

Registration date
2023-08-18, 1402/05/27

Registrant information

Name
Shima Rahmati

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 38 3224 5131

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rahmati.sh@skums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-05-22, 1402/03/01

Expected recruitment end date
2024-05-21, 1403/03/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation the Effect of Curcumin Capsules on Prevention of Nephropathy Caused by Chemotherapy with Cisplatin(double blind clinical trial)

Public title
Investigating the effect of curcumin capsules on cisplatin-induced kidney damage
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Cancer patients over 5 years of age who are being treated with cisplatin be the same in terms of medications and supplements taken Absence of kidney tumor No kidney failure
Exclusion criteria:
Diagnosing the presence of kidney stones in patients Patient non-cooperation
Age
From **5 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
50 cancer patients referring to Hajar Shahrekord Hospital are divided into two groups of 25 each by the permutation block randomization method with a size of 10. The randomization list will be prepared by random allocation software and people will be assigned to groups named A and B.
Blinding (investigator's opinion)
Double blinded
Blinding description
This study will be conducted in a double-blind manner. The objectives of the study will be explained to the participants. In order to blind the patients, curcumin and placebo capsules will be prepared from the same company in similar packaging. The participants will not know which intervention group they are in. Also, the researcher is not aware of the contents of the medicine package.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of the School of Medicine, Shahrekord University of Medical Sciences
Street address
Headquarters of Shahrekord University of Medical Sciences,Kashani Street, Shahrekord, Chaharmahal va Bakhtiary, Iran
City
Shahrekord
Province
Chahar-Mahal-va-Bakhtiari
Postal code
8815713471
Approval date
2022-07-27, 1401/05/05
Ethics committee reference number
IR.SKUMS.MED.REC.1401.037

Health conditions studied

1

Description of health condition studied
cancer
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Serum levels of sodium
Timepoint
before the intervention and 8 weeks after the intervention
Method of measurement
Measurement of serum sodium level with a Flame Photometer

2

Description
Serum levels of potassium
Timepoint
before the intervention and 8 weeks after the intervention
Method of measurement
Measurement of serum potassium level with a Flame Photometer

3

Description
Serum levels of calcium
Timepoint
before the intervention and 8 weeks after the intervention
Method of measurement
Measurement of serum calcium level with a Flame Photometer

4

Description
Serum levels of magnesium
Timepoint
before the intervention and 8 weeks after the intervention
Method of measurement
Measurement of serum magnesium level with a Flame Photometer

5

Description
Serum levels of creatinine
Timepoint
before the intervention and 8 weeks after the intervention
Method of measurement
Measurement of serum creatinine level with a Flame Photometer creatinine

6

Description
Serum levels of blood urea nitrogen
Timepoint
before the intervention and 8 weeks after the intervention
Method of measurement
Measurement of serum blood urea nitrogen level with a Flame Photometer creatinine

7

Description
A quantitative measure of GFR
Timepoint
before the intervention and 8 weeks after the intervention
Method of measurement
Absolute measurement of glomerular filtration rate (GFR) according to creatinine clearance formula (GFR=Ucr*v/Pcr*1440)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Cancer patients treated with cisplatin who will receive 80 mg curcumin capsules (Sina Curcumin Company) 2 times a day for 9 weeks.
Category
Treatment - Drugs

2

Description
Control group: Cancer patients treated with cisplatin who will placebo capsules (Sina Curcumin Company) 2 times a day for 9 weeks.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahrekord Hajar Hospital
Full name of responsible person
kiavash fekri
Street address
Kashani street, Shahrekord, Chaharmahal va Bakhtiary, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahre-kord University of Medical Sciences
Full name of responsible person
Elham Reisi
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Kashani street, Shahrekord, Chaharmahal va Bakhtiary, Iran
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raeisi.e@skums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahre-kord 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
Shima Rahmati
Position
Researcher Cancer Research Center
Latest degree
Ph.D.
Other areas of specialty/work
Medical Biotechnology
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Person responsible for scientific inquiries

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Associate professor
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Person responsible for updating data

Contact
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Shima Rahmati
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Research Assistant in Cancer Research Center
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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
To share the data and documents of this research, only the information related to the main outcome will be shared. Also, files that can be published and do not violate people's privacy will be published.
When the data will become available and for how long
The access period will start 6 months after the results are published.
To whom data/document is available
Our data will only be available to researchers working in academic and scientific institutions
Under which criteria data/document could be used
Except for personal information about people, all of our data will be shared if certain requirements are met. Our data will only be used for comparable study and peer review by other researchers. Anyone working in universities or scientific institutions who wants to do similar study or confirm the accuracy of our data can

access our data.

From where data/document is obtainable

All qualified individuals can collect data by referring to the project manager in order to acquire information. Contact information is available via email at shimarahmati1987@gmail.com or the contact number 00989139854865

What processes are involved for a request to access data/document

To receive information after sending the request, the requests will be reviewed within 10 days. If the above conditions are met, the information will be sent to the provided email within 30 days at most.

Comments