Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jul 2026

Curcumin in the prevention of cisplatin-induced acute nephrotoxicity: a randomized,double-blind, placebo-controlled clinical trial

Protocol summary

Study aim
The effect of curcumin on prevention of cisplatin-induced nephrotoxicity in patients receiving cisplatin

Design
This study is a controlled clinical trial. Randomization will be done by blocked randomization method. The predicted sample size of patients will be divided into two parallel groups of control and intervention group (intervention group).

Settings and conduct
This study is a controlled clinical trial. This study will be performed on hospitalized patients in hematology-oncology center of Seyyed al-Shohada hospital (affiliated to Isfahan University of Medical Sciences).

Participants/Inclusion and exclusion criteria
All adult patients with malignancy who will receive cisplatin in their treatment regimens at a dose of 50-100 mg and will be also able to receive curcumin orally will be included. Patients must have a renal clearance of above 45 mg/dl. Patients who would be infected during the study or exposed to bilirubin above 2.5 mg/dl or increased liver enzymes more than twice of the normal level will be excluded.

Intervention groups
Patients with malignancy who will receive cisplatin will identify and after signing the consent will be considered for intervention. Two hours before the start of cisplatin administration, the curcumin capsuls were administered to the patient in a dose of 160 mg daily (curcumin capsuls 80 mg 2 times daily). curcumin administration continued until 5 days after cisplatin administration. All patients will be treated with a cisplatin nephropathy preventive procedure including the same dose of 0.9% sodium chloride during treatment with this drug.

Main outcome variables
Reduction of the side effects (nephrotoxicity) of cisplatin with curcumin in cancer patients receiving cisplatin

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180722040556N8**
Registration date: **2022-02-04, 1400/11/15**
Registration timing: **prospective**

Last update: **2022-02-04, 1400/11/15**
Update count: **0**

Registration date
2022-02-04, 1400/11/15

Registrant information

Name
Azadeh Moghaddas

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 31 1792 7074

Email address
moghaddas@pharm.mui.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-02-20, 1400/12/01

Expected recruitment end date
2023-02-19, 1401/11/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Curcumin in the prevention of cisplatin-induced acute nephrotoxicity: a randomized,double-blind, placebo-controlled clinical trial

Public title

Curcumin in the prevention of cisplatin-induced acute nephrotoxicity

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Creatinine Clearance higher than 45 mL/min based on CKD-EPI (Chronic Kidney Disease Epidemiology Collaboration) The patient who will have enough compliance and ability to take curcumin orally. All adult cancer 's patients who will receive a regimen contains cisplatin (with the usual recommended dose between 50-100 mg / m2)

Exclusion criteria:

Patients with active infection or symptoms of sepsis. Patients who have received nephrotoxic drugs such as aminoglycoside, amphotericin, vancomycin, colistin, media contrast, calcineurin inhibitors or Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) for the past 72 hours. Patients who are taking ifosfamide in their chemotherapy regimen Patients who are taking fluvoxamine, anagrelide, or hydroxy progesterone in their treatment regimen. Patients who may experience complications or allergic reactions to curcumin during treatment. Patients who had a history of acute kidney injury (AKI) before entering the study. Patients with bilirubin above 2 mg / dl or liver enzymes above 2.5 times the normal level.

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Data and Safety Monitoring Board

Sample size

Target sample size: **100**

More than 1 sample in each individual

Number of samples in each individual: **3**

Three samples of blood and urine in times 0 and 24 hours and 5 days from bigining of study

Randomization (investigator's opinion)

Randomized

Randomization description

Sampling will be done by Blocked randomization method. Information such as the number of intervention groups (two main intervention groups, for example, A and control, for example, B), block size (multiple numbers of groups, in this study to reduce complexity, 4 will be selected). The total number of patients (sample size 60) will be entered into Internet-specific software for this calculation (for example, available at " the Create a blocked randomisation list | Sealed Envelope"). For each included patients, a specific code will be allocated in order to determine the type of included group. The predicted sample size of patients will be accomplished randomly by using this method. The main investigator will allocate the concealed code to control group or case group according to random numbers and will put them to investigators who is in charge of sampling.

Blinding (investigator's opinion)

Double blinded

Blinding description

For keeping participants, investigator and health care providers blind, whole curcumin capsules will be extracted from blister and separated in considered packages by the main investigator. Finally, all drugs and placebo packages will be labelled by codes extracted from internet-based software. After completion of recruitment, each patients code were coordinated with software data and investigator or health care providers will be informed after data analyses of drugs' codes.

Placebo

Used

Assignment

Parallel

Other design features

This study is a clinical trial. One-year sampling period on patients admitted or outpatient in hematology-oncology center of Seyyed al-Shohada hospital (affiliated to Isfahan University of Medical Sciences) or clinics affiliated to Isfahan University of Medical Sciences. This hospital is a 200 bed specialized and referral hospital for the treatment of patients with hematologic cancers or solid tumors. It is also well equipped in terms of medical staff and facilities to treat such patients.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Isfahan University of medical Scienices, Daneshgah street, Isfahan, Iran

City

Isfahan

Province

Isfehan

Postal code

8174673461

Approval date

2021-11-01, 1400/08/10

Ethics committee reference number

IR.MUI.RESEARCH.REC.1400.331

Health conditions studied

1

Description of health condition studied
Nephrotoxicity
ICD-10 code
N17.8
ICD-10 code description
Other acute kidney failure

Primary outcomes

1

Description
Incidence of cisplatin-induced renal injury according to cheng in Glomerular Filtration Rate (GFR)
Timepoint
Measurement of BUN, creatinine, in urine and serum at the time of the previous day, a day and five days after treatment with Cisplatin
Method of measurement
Measurement of urine and serum values by electrolyte analyzer and fordata analysis using Statistical Package for Social Sciences (SPSS)

Secondary outcomes

1

Description
The effect of curcumin on cisplatin-induced renal injury according to cheng in exertion rate of sodium
Timepoint
Measurement of sodium in urine and serum at the time of the previous day, a day and five days after treatment with Cisplatin
Method of measurement
Measurement of urine and serum values by electrolyte analyzer and fordata analysis using Statistical Package for Social Sciences (SPSS)

2

Description
The effect of curcumin on cisplatin-induced renal injury according to cheng in exertion rate of potassium
Timepoint
Measurement of potassium in urine and serum at the time of the previous day, a day and five days after treatment with Cisplatin
Method of measurement
Measurement of urine and serum values by electrolyte analyzer and fordata analysis using Statistical Package for Social Sciences (SPSS)

3

Description
The effect of curcumin on cisplatin-induced renal injury according to cheng in exertion rate of magnesium
Timepoint
Measurement of magnesium in urine and serum at the time of the previous day, a day and five days after treatment with Cisplatin
Method of measurement
Measurement of urine and serum values by electrolyte analyzer and fordata analysis using Statistical Package for Social Sciences (SPSS)

Intervention groups

1

Description
Intervention group: Patients with malignancy who will receive cisplatin with the dose 50-100 mg/m2 will be identified and after signing the consent will be considered for intervention. Two hours before the start of cisplatin administration, the curcumin capsuls from Exir nano sina pharmaceutical company were administered to the patient in a dose of 160 mg daily (curcumin capsuls 80 mg 2 times daily). Curcumin administration continued until 5 days after cisplatin administration. All patients will be treated with a cisplatin nephropathy preventive procedure including the 0.9% sodium chloride during treatment with this drug. In the control group, the routine treatment ward protocol including 2 lit of 0.9% sodium chloride serum during cisplatin administration without placebo will be administra
Category
Prevention

2

Description
Control group: Patients with malignancy who will receive cisplatin will identify and after signing the consent will be considered for intervention.All patients will be treated with a cisplatin nephropathy preventive procedure including the same dose of 0.9% sodium chloride during treatment with this drug. in this group patient won't receive curcumin .
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Seyed al-Shohada Teaching Hospital - Hazrat Zahra Special Clinic
Full name of responsible person
Azade Moghaddas
Street address
Hezarjarib
City
Isfahan
Province
Isfehan
Postal code

۷۳۴۶۱-۸۱۷۴۶

Phone
+98 31 3792 7470

Email
moghaddas@pharm.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Shaghayegh Haghjou

Street address
Isfahan University of medical Sciences, Hezar jarib street, Isfahan, Iran

City
Isfahan

Province
Isfehan

Postal code
73461-81746

Phone
+98 31 3668 0048

Email
moghaddas@pharm.mui.ac.ir

Grant name
Vice-Chancellery for Research of Isfahan University of Medical Sciences

Grant code / Reference number

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

Title of funding source
Esfahan 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
Esfahan University of Medical Sciences

Full name of responsible person
Azade Moghaddas

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Hematology

Street address
Faculty of Pharmacy, Isfahan University of medical Sciences, Hezar jarib street, Isfahan, Iran

City
Isfahan

Province
Isfehan

Postal code
81746-73461

Phone
+98 31 3792 7074

Email
moghaddas@pharm.mui.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Azade Moghaddas

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Hematology

Street address
Isfahan University of Medical Sciences, Hezar Jarib Street, Isfahan

City
Isfahan

Province
Isfehan

Postal code
81746-73461

Phone
+98 31 3792 7074

Email
moghaddas@pharm.mui.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Azadeh Moghaddas

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Hematology

Street address
Isfahan University of medical Sciences, Hezar jarib street, Isfahan, Iran

City
Isfahan

Province
Isfehan

Postal code
81746-73461
Phone
+98 31 3792 7074
Email
moghaddas@pharm.mui.ac.ir

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
All collected data
When the data will become available and for how long
From the summer of 2021
To whom data/document is available
All academic centers
Under which criteria data/document could be used
All documents with citation
From where data/document is obtainable
E-mail address
What processes are involved for a request to access data/document
After sending a request, we will call the related person and the data will be revealed in less than one week.
Comments