

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 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 capsules were administered to the patient in a dose of 160 mg daily (curcumin capsules 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 Isfahan 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 change 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 for data analysis using Statistical Package for Social Sciences (SPSS)

Secondary outcomes

1

Description

The effect of curcumin on cisplatin-induced renal injury according to change in excretion 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 for data analysis using Statistical Package for Social Sciences (SPSS)

2

Description

The effect of curcumin on cisplatin-induced renal injury according to change in excretion 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 for data analysis using Statistical Package for Social Sciences (SPSS)

3

Description

The effect of curcumin on cisplatin-induced renal injury according to change in excretion 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 for data 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 capsules from Exir nano sina pharmaceutical company were administered to the patient in a dose of 160 mg daily (curcumin capsules 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 administered

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

Isfahan

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

Isfahan

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

Isfahan

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

Isfahan

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

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Province

Isfahan

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