

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

Evaluation of Curcumin effectiveness in prophylaxis of Cisplatin induced renal toxicity

Protocol summary

Study aim

Evaluation of curcumin effectiveness in prophylaxis of cisplatin induced renal toxicity

Design

Control-controlled clinical trial with parallel, double-blind, randomized, phase 3 groups on 34 patients used the Excel software rand function for randomization.

Settings and conduct

This project has been carried out at Shahid Sadoughi Hospital in Yazd and Shahid Ramezanzadeh Radiation Center in Yazd. Patients in two groups of 17 receive curcumin or placebo every 12 hours.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients 18 to 80 years old to get started chemotherapy with Cisplatin The patient satisfaction
Exclusion criteria: GFR less than 45ml / min

Intervention groups

Intervention group: Patients receiving curcumin capsules (500mg)
Control group: Patients receiving placebo capsules

Main outcome variables

Decreased urinary calcium
Decreased urinary sodium
Decreased urinary potassium
Decreased urinary magnesium

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181208041882N4**
Registration date: **2021-09-26, 1400/07/04**
Registration timing: **retrospective**

Last update: **2021-09-26, 1400/07/04**

Update count: **0**

Registration date

2021-09-26, 1400/07/04

Registrant information

Name

behrooz heydari

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-11-21, 1399/09/01

Expected recruitment end date

2021-02-28, 1399/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Curcumin effectiveness in prophylaxis of Cisplatin induced renal toxicity

Public title

Evaluation of Curcumin effectiveness in prophylaxis of renal toxicity

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Patients 18 to 80 years old to get started chemotherapy with Cisplatin The patient satisfaction

Exclusion criteria:

Active infection
Heart failure
Liver failure
Taking other nephrotoxic drugs

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **34**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, 34 patients are randomly divided into two treatment groups (A and B). Block random allocation method will be used for random allocation. In this study, 7 blocks of 5 are considered. The generated permutations include repeated letters A and B (eg ABAAB). These permutations are generated with the help of Random allocation software version 1. For this purpose, the list prepared by the software is from 1 to 34, which are arranged in 7 blocks of five regularly. To run this software output, we give the first qualified person number 1 and the last person will receive number 34. In order to be blind, the random allocation of this list is given to another person outside the study, and by sending a text message before assigning the type of treatment, the eligible person is asked according to the number, and thus the people enter the study. Also in the software output, both numbers 1 to 34 and permutations of the letters A and B can be seen.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study patients, clinical caregivers and outcome assessors were unaware of the type of medication patients were receiving. Patients in both groups received the medication in the same package

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Yazd University of Medical Sciences

Street address

Shahid Sadoughi University of Medical Science, Shohadaye Gornam Blvd, Alem Sq

City

Yazd

Province

Yazd

Postal code

8915173143

Approval date

2019-03-10, 1397/12/19

Ethics committee reference number

IR.SSU.MEDICINE.REC.1398.081

Health conditions studied**1****Description of health condition studied**

Nephrotoxicity caused by cisplatin injection

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Measurement of urinary protein NGAL (Neutrophil gelatinase-associated lipocalin) . In acute kidney damage, the protein is released from the damaged kidney cells after 2 hours and enters the urine.

Timepoint

Measurement of urinary NGAL two days before and two days after cisplatin injection

Method of measurement

Based on the ELISA diagnostic kit

2**Description**

Measurement Mg Urinary Random

Timepoint

Two days before and two days after Cisplatin injection

Method of measurement

Laboratory data

3**Description**

Measurement Ca Urinary Random

Timepoint

two Days before and two Days after Cisplatin injection

Method of measurement

Laboratory data

4**Description**

Measurement Na Urinary Random

Timepoint

two Days before and two Days after Cisplatin injection

Method of measurement

Laboratory data

5**Description**

Measurement K Urinary Random

Timepoint

two Days before and two Days after Cisplatin injection

Method of measurement

Laboratory data

Secondary outcomes

empty

Intervention groups**1****Description**

Patients start taking curcumin capsules (500mg, Karen company) orally twice daily from two days before cisplatin injection and continue for 4 days.

Category

Prevention

2**Description**

Control group: Patients start taking placebo capsules (Karen company) orally twice daily from two days before cisplatin injection and continue for 4 days.

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shahid Sadoughi hospital Yazd, Shahid Ramezanzadeh Radiotherapy Center, Yazd

Full name of responsible person

Hasanali vahedian. Masoud shabani .Mohammad ali broomand

Street address

Yazd, Safaieh, Shahid Ghandi Boulevard, Ibn Sina Street, Yazd Azadi Sq Shahid Mottahari Street

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shabanimasood@gmail.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Yazd University of Medical Sciences

Full name of responsible person

Masoud Mirzaei

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Yazd 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**

Yazd University of Medical Sciences

Full name of responsible person

Behrooz Heydari

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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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

After nonrecognition, all data can be share

When the data will become available and for how long

6 months after publication

To whom data/document is available

All of researchers

Under which criteria data/document could be used

Nothing

From where data/document is obtainable

Behrooz Heydari email: b.heydari@ssu.ac.ir

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

Request your information by email. The data will be sent after a week.

Comments