

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Aug 2026

Evaluation of oral nano-curcumin formulation efficacy in prevention of cisplatin induced nephrotoxicity in cancer patients

Protocol summary

Study aim

Evaluation of oral nano-curcumin formulation efficacy in prevention of cisplatin induced nephrotoxicity in cancer patients.

Design

The clinical trial has a control group with parallel groups, triple blinded, randomized, phase 2 on 30 patients. Randomization.com site was used for randomization.

Settings and conduct

30 patients aged 18-60 with cancers referred to the Oncology and Radiotherapy Clinic of Imam Reza, who met the inclusion criteria. Patients are randomly assigned to the placebo or drug. The chemotherapy regimen of all patients contains cisplatin at the rate of 40 mg/m² per week.

Participants/Inclusion and exclusion criteria

To enter the study: Chemotherapy regimen cisplatin dose of 70mg/m² every three weeks or 40mg/m² weekly, Age above 18 years and below 70 years, GFR>60 ml/min, Normal liver function, Normality of patients' CBC Not entering the study: Allergy to curcumin, Patient dissatisfaction, Reduction of patient's GFR below 45ml/min during treatment, Receiving other nephrotoxic drugs such as aminoglycosides, amphotericin, vancomycin-Chronic heart failure EF<60%, Untreated hypothyroidism or hyperthyroidism Active infection, Receiving anti-inflammatory and antioxidant drugs at the same time Unfavorable health status (PS<70%) based on karnofsky index.

Intervention groups

intervention group: two capsules of cinacurcumin 40 mg are prescribed for six chemotherapy courses. In the control group, two placebo capsules are prescribed per day that are filled with cinacurcumin carrier with the same appearance as the original drug.

Main outcome variables

Serum creatinine and BUN levels will be recorded at the beginning of the study. The patient's kidney status will be evaluated every three weeks at the same time as the

chemotherapy courses based on serum creatinine and BUN levels.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200408046990N11**

Registration date: **2022-10-08, 1401/07/16**

Registration timing: **retrospective**

Last update: **2022-10-08, 1401/07/16**

Update count: **0**

Registration date

2022-10-08, 1401/07/16

Registrant information

Name

Sepideh Elyasi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3180 1588

Email address

elyasis@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-21, 1399/03/01

Expected recruitment end date

2022-04-21, 1401/02/01

Actual recruitment start date

2020-05-21, 1399/03/01

Actual recruitment end date

2022-04-21, 1401/02/01

Trial completion date

2022-05-08, 1401/02/18

Scientific title

Evaluation of oral nano-curcumin formulation efficacy in prevention of cisplatin induced nephrotoxicity in cancer patients

Public title

Observing the effect of nanocurcumin oral product in preventing cisplatin nephrotoxicity in cancer patients

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with cancer and candidates for chemotherapy with regimen containing cisplatin at a dose of 70mg/m² every three weeks or 40mg/m² weekly Patient age above 18 years and below 70 years GFR>60 ml/min At the start of chemotherapy Normal liver function Normality of patients' CBC

Exclusion criteria:

Allergy to curcumin Patient dissatisfaction Reduction of patient's GFR below 45ml/min during treatment Receiving other nephrotoxic drugs such as aminoglycosides, amphotericin, vancomycin Patients with chronic heart failure EF<60% Patients with untreated hypothyroidism or hyperthyroidism Patients with active infection Receiving anti-inflammatory and antioxidant drugs at the same time Unfavorable health status (PS<70%) based on karnofsky index

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **40**

Actual sample size reached: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization using Randomization.com will implemented. This method uses simple randomization models such as head or tail, using a random number table or using computer randomization methods, and for example, each client by dropping coin will include in control or intervention group. This method is very simple to implement. Patients will receive enrollment number 1 or 2, respectively, and enter one of two groups of drugs or placebo.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Nano-curcumin and placebo soft gels packages in identical bottle will be delivered to the clinician. Patients

who meet the inclusion criteria will be selected by clinician to be included in the study, randomly assigned to a drug or placebo group and be given a bottle with A or B mark. The physician and the resident of clinical pharmacy will evaluate patients in the course of treatment. Data collection and analysis will be performed by the clinical pharmacy resident and the clinical pharmacist. All of them will be unaware that A or B is on medication or placebo until the end of the study and data analysis.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Mashhad University of Medical Science

Street address

Qureshi Building, Daneshgah street, Mashhad, Iran

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Mashhad

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Razavi Khorasan

Postal code

1394491388

Approval date

2020-04-26, 1399/02/07

Ethics committee reference number

IR.MUMS.REC.1399.163

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

Cancer

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

Serum ceratinine level, BUN

Timepoint

At the beginning of each chemotherapy course

Method of measurement

Blood test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: in the intervention group, two 40mg synacorcumins capsules per day, made by Elixir Nano Sinat, are prescribed for six chemotherapy courses, and in the control group, two placebo capsules are prescribed per day, which are filled with sinacorcumins carrier and by Elixir Nano Sina factory. They are manufactured to look similar to the original drug and are prescribed for six chemotherapy courses

Category

Prevention

2

Description

Control group: In the placebo control group, two placebo capsules per day, which look similar to the drug capsules and contain all the ingredients in the medicine except the active ingredient, are prescribed for six chemotherapy courses.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Sare Hosseini

Street address

Imam Reza Hospital, Shariati Square, Mashhad, Iran

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2

Recruitment center

Name of recruitment center

Omid Hospital

Full name of responsible person

Sare Hosseini

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Majid Ghayour-Mobarhan

Street address

Ghoreishi building, Daneshgah street, Mashhad, Iran

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ghayourm@mums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Sare Hosseini

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Radiotherapy

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

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Position

Associate Professor

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

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

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available