Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Jun 2026

Evalution of oral nano-curcumin formulation efficacy in prevention of cisplatin induced nephrotixicity in cancer patients

Protocol summary

Study aim

Evalution 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 cinacorcumin 40 mg are prescribed for six chemotherapy courses.in the control group, two placebo capsules are prescribed per day that are filled with cinacorcumin 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
Evalution of oral nano-curcumin formulation efficacy in prevention of cisplatin induced nephrotixicity 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 chemotherapyNormal liver function Normality of patients' CBC

Exclusion criteria:
Allergy to curcuminPatient dissatisfactionReduction of patient's GFR below 45ml/min during treatmentReceiving other nephrotoxic drugs such as aminoglycosides, amphotericin, vancomycin Patients with chronic heart failure EF<60%Patients with untreated hypothyroidism or hyperthyroidismPatients with active infectionReceiving anti-inflammatory and antioxidant drugs at the same timeUnfavorable 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

City
Mashhad

Province
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 synacorcumin 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 sinacorcumin 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
City
Mashhad
Province
Razavi Khorasan
Postal code
9137913316
Phone
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Email
hosseinis@mums.ac.ir

2

Recruitment center
Name of recruitment center
Omid Hospital
Full name of responsible person
Sare Hosseini
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Kouhsangi Street
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hosseinis@mums.ac.ir

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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9138813944
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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

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Full name of responsible person
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Position
Associate Professor

Latest degree
Specialist

Other areas of specialty/work
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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