Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Evaluation of the effects of curcumin supplementation on oxidative stress indices in patients treated with cisplatin: a double-blind, placebo-controlled randomized clinical trial

Protocol summary

Study aim
Determining the effects of curcumin supplementation on oxidative stress indices in patients treated with cisplatin

Design
Randomized, double-blinded, parallel, placebo-controlled clinical trial phase 2 with 25 patients in each group. .Randomization will be done by blocked randomization method.

Settings and conduct
This study is a controlled clinical trial. This study will be performed on hospitalized patients in the hematology-oncology center of Seyyed al-Shohada hospital (affiliated with 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.

Main outcome variables
Parameters of oxidative stress will be quantified at the study baseline and end-of-trial.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190305042939N2**
Registration date: **2022-07-14, 1401/04/23**
Registration timing: **prospective**

Last update: **2022-07-14, 1401/04/23**
Update count: **0**

Registration date
2022-07-14, 1401/04/23

Registrant information

Name
Mohamad hosein aarabi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-07-23, 1401/05/01

Expected recruitment end date
2023-06-22, 1402/04/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the effects of curcumin supplementation on

oxidative stress indices in patients treated with cisplatin: a double-blind, placebo-controlled randomized clinical trial

Public title
Curcumin supplementation in cancer patients under cisplatin treatment
Purpose
Diagnostic
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with malignancy who receive cisplatin for the first time in their treatment regimens GFR higher than 60 mL/min based on CKD-EPI (Chronic Kidney Disease Epidemiology Collaboration) The patient be able to receive curcumin orally
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 have a history of taking cisplatin 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 The patient's unwillingness to cooperate during the research 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
- Outcome assessor

Sample size
Target sample size: **50**
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 50) will be entered into Internet-specific software for this calculation. 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
In order for the patient, researcher and the intervening physician to remain blind in the intervention, all curcumin capsules are separated from the blister and the placebo is prepared in a series of pre-prepared medicine containers completely similar to the original drug form by the executor. The intervening physician, researcher, and patients are kept blind to the type of drug (main or placebo) and the type of grouping A and B (which is the main group and which group is a placebo).
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences
Street address
Deputy of Research & Technology, Headquarters Building No. 4, Isfahan University of Medical Sciences & Health Services, Isfahan
City
Isfehan
Province
Isfehan
Postal code
8174673461
Approval date
2022-03-05, 1400/12/14
Ethics committee reference number
IR.MUI.RESEARCH.REC.1400.499

Health conditions studied

1

Description of health condition studied
Cancer types
ICD-10 code
C56, C50
ICD-10 code description
Malignant neoplasm of ovary, Malignant neoplasm of breast

Primary outcomes

1

Description
Total antioxidant capacity: A set of compounds that are

able to protect biological systems against the harmful effects of reactive oxygen and nitrogen species .

Timepoint

Baseline and End-of-trial

Method of measurement

Total antioxidant capacity testing is performed through commercially available kits and the ELISA reader.

2

Description

Malondialdehyde (MDA): One of the most common lipid indicators of oxidative stress.

Timepoint

Baseline and End-of-trial

Method of measurement

Serum malondialdehyde levels are assessed through commercially available kits and an ELISA reader.

3

Description

Activity of catalase enzyme: It is an antioxidant enzyme involved in the detoxification of hydrogen peroxide (the reactive oxygen species).

Timepoint

Baseline and End-of-trial

Method of measurement

Catalase activity is assessed through commercially available kits and an ELISA reader.

4

Description

Activity of super oxide dismutase enzyme: It is an enzyme that converts superoxide free radicals to hydrogen peroxide and oxygen molecules.

Timepoint

Baseline and End-of-trial

Method of measurement

super oxide dismutase activity is assessed through commercially available kits and an ELISA reader.

Secondary outcomes

1

Description

Expressed levels of interleukin-6 gene

Timepoint

Baseline and End-of-trial

Method of measurement

We first synthesize RNA molecules with the help of reverse transcriptase enzyme (MMLV enzyme) and convert them into complementary DNAs called cDNAs. Then, with the help of Realtime PCR, we examine the expression of the target gene.

2

Description

Expressed levels of NRF-2 gene

Timepoint

Baseline and End-of-trial

Method of measurement

We first synthesize RNA molecules with the help of reverse transcriptase enzyme (MMLV enzyme) and convert them into complementary DNAs called cDNAs. Then, with the help of Realtime PCR, we examine the expression of the target gene.

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.

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.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

Mohammadhosein Aarabi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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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
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
Mohamadhosein Araabi

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Biochemistry

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Person responsible for scientific inquiries

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Person responsible for updating data

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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
Not applicable
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
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Not applicable
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 2022
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
Through the registered e-mail address (Person responsible for scientific inquiries) and the request to the responsible author, the required documents or data will be provided to the person in less than one week.
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