# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

16 Sep 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**

**Country**
Iran (Islamic Republic of)

**Phone**
+98 31 3792 7052

**Email address**
mh.aarabi@pharm.mui.ac.ir

**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

**Street address**

Seyedoshohada hospital, Khayam street, Isfahan

**City**

Isfehan

**Province**

Isfehan

**Postal code**

8434193474

**Phone**

+98 31 3668 5555

**Email**

Mh.aarabi@pharm.mui.ac.ir

## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**
Esfahan University of Medical Sciences

**Full name of responsible person**
Mansour Siavash Dastjerdi

**Street address**
Deputy of Research & Technology Headquarters Building No. 4, Isfahan University of Medical Sciences & Health Services, Isfahan

**City**
Isfahan

**Province**
Isfehan

**Postal code**
8174673461

**Phone**
+98 31 3668 5149

**Email**
Research@mui.ac.ir

**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

**Street address**
Department of Clinical Biochemistry, School of Pharmacy and Pharmaceutical Sciences, Isfahan University of Medical Sciences, Hezar jarib St, Isfahan

**City**
Isfahan

**Province**
Isfehan

**Postal code**
8174673441

**Phone**
+98 31 3792 7052

**Fax**

**Email**
mh.aarabi@pharm.mui.ac.ir

## Person responsible for scientific 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

**Street address**
Department of Clinical Biochemistry, School of Pharmacy and Pharmaceutical Sciences, Isfahan University of Medical Sciences, Hezar jarib St, Isfahan

**City**
Isfahan

**Province**
Isfehan

**Postal code**
8174673441

**Phone**
+98 31 3792 7052

**Fax**

**Email**
mh.aarabi@pharm.mui.ac.ir

## Person responsible for updating data

**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

**Street address**
Department of Clinical Biochemistry, School of Pharmacy and Pharmaceutical Sciences, Isfahan University of Medical Sciences, Hezar jarib St, Isfahan

**City**
Isfahan

**Province**
Isfehan

**Postal code**
8174673441

**Phone**
+98 31 3792 7052

**Fax**

**Email**
mh.aarabi@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**
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**