

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Evaluation of the protective effect of Curcuma Longa against cisplatin induced nephrotoxicity in patients with cancer

#### Protocol summary

##### Study aim

Evaluation of the protective effect of Curcuma Longa against cisplatin induced nephrotoxicity in patients with cancer

##### Design

Clinical trial with a control group, with parallel groups, one-way blind, randomized, on 30 patients (2 groups of 15 people). Patients are allocated randomly with simple sequential allocation in one of the two study groups by help of sealed envelope.

##### Settings and conduct

This study will be performed as a clinical trial in Kosar Hospital in Semnan. Patients are unaware of the intervention groups. Variables are measured before starting cisplatin treatment and also at 5 and 21 days after starting cisplatin treatment.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 18-60 years; Confirmation of cancer by a specialist doctor; The disease should be such that the use of cisplatin as a treatment is approved by a specialist doctor. Exclusion criteria: The patient has a previous kidney disease (GFR is low from the beginning); Existence of underlying diseases such as diabetes, hypertension, etc. in the patient; Increased creatinine indicated for discontinuation of the drug.

##### Intervention groups

Intervention group: In addition to routine treatments, this group consumes one turmeric tablet of "Dineh Iran" company (Each tablet contains 450 mg of turmeric rhizome powder and 50 mg of turmeric extract, which is standardized based on 5.47 mg of curcumin) with lunch 3 days before the start of cisplatin treatment. Control group: This group only receives routine treatments.

##### Main outcome variables

Blood creatinine level; BUN(Blood Urea Nitrogen) level; Creatinine Clearance level.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20151228025732N70**

Registration date: **2021-12-07, 1400/09/16**

Registration timing: **registered\_while\_recruiting**

Last update: **2021-12-07, 1400/09/16**

Update count: **0**

##### Registration date

2021-12-07, 1400/09/16

##### Registrant information

##### Name

Alireza Emadi

##### Name of organization / entity

Semnan University of Medical Sciences, Semnan, Iran

##### Country

Iran (Islamic Republic of)

##### Phone

+98 23 3345 1336

##### Email address

are20935@semums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-12-06, 1400/09/15

##### Expected recruitment end date

2022-02-04, 1400/11/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Evaluation of the protective effect of Curcuma Longa against cisplatin induced nephrotoxicity in patients with cancer

## Public title

Evaluation of the protective effect of Curcuma Longa induced nephrotoxicity in patients with cancer

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Age 18-60 years Confirmation of cancer by a specialist doctor The disease should be such that the use of cisplatin as a treatment is approved by a specialist doctor

### Exclusion criteria:

The patient has a previous kidney disease (GFR is low from the beginning) Existence of underlying diseases such as diabetes, hypertension, etc. in the patient Increased creatinine indicated for discontinuation of the drug

## Age

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

## Gender

Both

## Phase

N/A

## Groups that have been masked

- Participant

## Sample size

Target sample size: **30**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Numbers 1 to 30 are written on paper and all of them are placed in sealed envelopes. Patients are then asked to select an envelope each. Patients whose number in the envelope is odd will be in the intervention group and patients whose number in the envelope is even will be in the control group.

## Blinding (investigator's opinion)

Single blinded

## Blinding description

Drug packaging is coded. So that the patients are unaware of the drug content packaging and intervention that they receive.

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

## 1

### Ethics committee

#### Name of ethics committee

Ethics committee of Semnan University of Medical Sciences

#### Street address

Semnan University of Medical Sciences, Basij Blvd, Semnan

#### City

Semnan

#### Province

Semnan

#### Postal code

3514799442

#### Approval date

2020-10-27, 1399/08/06

#### Ethics committee reference number

IR.SEMUMS.REC.1399.218

## Health conditions studied

## 1

### Description of health condition studied

Cisplatin induced nephrotoxicity

#### ICD-10 code

N17.9

#### ICD-10 code description

Acute kidney failure, unspecified

## Primary outcomes

## 1

### Description

Blood creatinine level

### Timepoint

Before starting treatment with Cisplatin and 5 and 21 days after starting treatment with Cisplatin

### Method of measurement

Biorexfars Laboratory Diagnostic Kit

## 2

### Description

BUN(Blood Urea Nitrogen) level

### Timepoint

Before starting treatment with Cisplatin and 5 and 21 days after starting treatment with Cisplatin

### Method of measurement

Biorexfars Laboratory Diagnostic Kit

## 3

### Description

Creatinine Clearance level

### Timepoint

Before starting treatment with Cisplatin and 5 and 21 days after starting treatment with Cisplatin

### Method of measurement

Through Up-to-date software and using the CKD-EPI formula

## Secondary outcomes

empty

## Intervention groups

1

### Description

Intervention group: In addition to routine treatments, this group consumes one turmeric tablet of "Dineh Iran" company (Each tablet contains 450 mg of turmeric rhizome powder and 50 mg of turmeric extract, which is standardized based on 5.47 mg of curcumin) with lunch 3 days before the start of cisplatin treatment.

### Category

Treatment - Drugs

2

### Description

Control group: This group only receives routine treatments

### Category

Treatment - Other

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Kowsar Hospital

#### Full name of responsible person

Seyed Ali Madani Lamraski

#### Street address

Street Amin, Semnan

#### City

Semnan

#### Province

Semnan

#### Postal code

3519899951

#### Phone

+98 23 3345 1336

#### Email

are20935@gmail.com

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Semnan University of Medical Sciences

#### Full name of responsible person

Parviz Kokhaei

#### Street address

Semnan University of Medical Sciences, Basij Blvd,  
Semnan.

#### City

Semnan

### Province

Semnan

### Postal code

3514799442

### Phone

+98 23 3345 1336

### Email

p\_kokha@yahoo.com

### Grant name

### Grant code / Reference number

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

Yes

### Title of funding source

Semnan 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

Semnan University of Medical Sciences

#### Full name of responsible person

Mohammad Amir Sarabi

#### Position

Associate professor

#### Latest degree

Subspecialist

#### Other areas of specialty/work

Hematology

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Street Amin, Semnan

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## Person responsible for scientific inquiries

### Contact

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Mohammad Amir Sarabi

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**Person responsible for updating data**

**Contact**

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Mohammad Amir Sarabi

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**Latest degree**

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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**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available