

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jun 2026

### Preventive effect of lycopene on cisplatin nephrotoxicity in cancer patient

#### Protocol summary

##### Summary

**Objectives-** This trial was designed for assessment of lycopene effect on cisplatin induced nephropathy Design- Clinical randomized trial, not blinded, mono centric, without placebo. **Participants-** 120 people were selected from the patients referring to the hematology and oncology clinic of the Shahrekord university of medical sciences by convenience sampling. The inclusion criteria were patients to be suffering cancer without primary involvement or renal metastasis; being candidate for administration of 70-100 mg/m<sup>2</sup> cisplatin; being 20-80 years old; Cr < 1.5; normal hearing; no underlying nephropathy; and the performance status of 0-2. **Exclusion criteria** were occurring death; allergy to lycopene; hearing loss; significant neuropathy; metastatic kidney involvement. **Intervention-** We assigned the patients randomly into two groups of cases and controls. The control group was treated with cisplatin and a standard regimen of kidney injury prevention (hydration+ sulphate magnesium). The case group were administered with 25mg twice a day lycopene 24hrs before until 72hrs after cisplatin injection+ cisplatin alongside a regimen of kidney injury prevention (hydration+ sulphate magnesium). **Variables-** Serum Cr, BUN measured when admission then after 3 and 21 days. GFR calculated with Crockroft-Gault formula.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016050427745N1**  
Registration date: **2016-07-31, 1395/05/10**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-07-31, 1395/05/10

#### Registrant information

##### Name

Leyla Mahmoodnia

##### Name of organization / entity

Shahrekord university of medical sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 38 3222 0016

##### Email address

mahmoodnia.l@skums.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Shahr-e-Kord medical university

#### Expected recruitment start date

2015-09-23, 1394/07/01

#### Expected recruitment end date

2016-03-20, 1395/01/01

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Preventive effect of lycopene on cisplatin nephrotoxicity in cancer patient

#### Public title

Lycopene nephrotoxicity prevention in cancer patients

#### Purpose

Prevention

#### Inclusion/Exclusion criteria

The inclusion criteria were considered to be suffering cancer without primary involvement or renal metastasis; being candidate for administration of 70-100 mg/m<sup>2</sup> cisplatin; being 20-80 years old; Cr < 1.5; normal hearing; no underlying nephropathy; ; performance status of 0-2. Exclusion criteria were death; allergy to

lycopene; hearing loss; moderate to severe neuropathy; renal metastatic involvement.

### Age

From **20 years** old to **80 years** old

### Gender

Both

### Phase

2-3

### Groups that have been masked

*No information*

### Sample size

Target sample size: **120**

### Randomization (investigator's opinion)

Randomized

### Randomization description

### Blinding (investigator's opinion)

Not blinded

### Blinding description

### Placebo

Not used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Medical ethics committee of Shahrekord university of medical sciences

##### Street address

Central organization of medical university, Kashani st.

##### City

Shahrekord

##### Postal code

8815713471

##### Approval date

2016-02-22, 1394/12/03

##### Ethics committee reference number

IR.SKUMS.rec.1394.271

## Health conditions studied

### 1

#### Description of health condition studied

Drug induced nephropathy

#### ICD-10 code

N14.1

#### ICD-10 code description

Nephropathy induced by other drugs, medicaments and biological substances

## Primary outcomes

### 1

#### Description

BUN

#### Timepoint

Before intervention, 7 & 21 days lft

#### Method of measurement

mg/dl - labratuary

### 2

#### Description

Cr

#### Timepoint

Before intervention, 7 & 21 days lft

#### Method of measurement

mg/dl - labratuary

### 3

#### Description

GFR

#### Timepoint

Before intervention, 7 & 21 days lft

#### Method of measurement

ml/min - calculation

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Lycopene 25mg tablet bid 24hr before until 72hr left after cisplatin injection and an standard regimen of kidney injury prevention (hydration+sulphate magnesium).

#### Category

Treatment - Drugs

### 2

#### Description

Cisplatin and an standard regimen of kidney injury prevention (hydration+sulphate magnesium).

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Emam Ali medical clinic

##### Full name of responsible person

Mrs. Fatemeh Nasiri

**Street address**

Emam Ali medical clinic, Shariaati st, Shahrekord

**City**

Shahrekord

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Vice chancellor for research, Shahrekord university of medical sciences

**Full name of responsible person**

Dr. Kamal Solatti

**Street address**

Central organization of medical university, Kashani st.

**City**

Shahrekord

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice chancellor for research, Shahrekord university of medical sciences

**Proportion provided by this source**

100

**Public or private sector***empty***Domestic or foreign origin***empty***Category of foreign source of funding***empty***Country of origin****Type of organization providing the funding***empty***Person responsible for general inquiries****Contact****Name of organization / entity**

Shahrekord university of medical sciences

**Full name of responsible person**

Keivan Mohammadi

**Position**

MD

**Other areas of specialty/work****Street address**

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**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

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Shahrekord university of medical sciences

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**Web page address****Sharing plan****Deidentified Individual Participant Data Set (IPD)***empty***Study Protocol***empty***Statistical Analysis Plan***empty***Informed Consent Form***empty***Clinical Study Report***empty***Analytic Code***empty***Data Dictionary***empty*