

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/m² 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)

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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/m² 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

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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*