

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 2026

### Evaluation of the nephroprotective effect of lycopene in patients receiving vancomycin

#### Protocol summary

##### Study aim

Determination of nephroprotective effect of lycopene in patients receiving vancomycin

##### Design

A clinical trial with an intervention groups and one control group, in parallel, double blinded, simple randomized groups and sample size of 60

##### Settings and conduct

This study is performed on patients at Alzahra Hospital. The subjects will be randomly assigned to two groups: lycopene and control. For people in the case group, lycopene tablets 15 mg once a day and for the control group placebo at the same dose accompanying vancomycin will be prescribed. Before starting treatment, every other day during treatment and 12 hours after the last dose of vancomycin on the tenth day of treatment with this antibiotic, blood samples were taken from both groups of patients and serum creatinine and blood urea nitrogen levels will be measured.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Serum creatinine levels less than 1.2 mg/dl at the start of the study; Creatinine clearance (ClCr)>90 ml / min upon admission; Lack of underlying renal impairment; Lack of underlying diseases causes kidney disorders such as diabetes mellitus and high blood pressure; Hospital history and failure to receive other nephrotoxic drugs such as aminoglycosides, amphotericin B, cyclosporine, tacrolimus and furosemide, etc; Do not take other antioxidant supplements such as vitamins C and E; Exclusion criteria: History of acute kidney damage; Lycopene allergy history; History of injectable addiction

##### Intervention groups

The subjects are randomly divided into two groups. The first group will receive lycopene, made by the 21st century factory, at a dose of 15 mg once daily, and the control group will receive placebo, which is made from starch and lactose by the Isfahan School of Pharmacy, at the same dose as lycopene and vancomycin.

#### Main outcome variables

Serum creatinine; Blood urea nitrogen; Creatinine clearance

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20171030037093N37**

Registration date: **2020-05-04, 1399/02/15**

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

Last update: **2020-05-04, 1399/02/15**

Update count: **0**

##### Registration date

2020-05-04, 1399/02/15

##### Registrant information

##### Name

Sadra Ansari pour

##### Name of organization / entity

Shahrekord University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3650 3487

##### Email address

st\_ansari.s@skums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-04-28, 1399/02/09

##### Expected recruitment end date

2021-04-19, 1400/01/30

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Evaluation of the nephroprotective effect of lycopene in patients receiving vancomycin

**Public title**

Lycopene nephroprotective effect in patients receiving vancomycin

**Purpose**

Prevention

**Inclusion/Exclusion criteria****Inclusion criteria:**

Serum creatinine levels less than 1.2 mg / dl at the start of the study Creatinine clearance (ClCr)> 90 ml / min upon admission Lack of underlying renal impairment such as glomerulonephritis, polycystic kidney disease, kidney stones, interstitial nephritis, renal artery stenosis and renal carcinoma Lack of underlying diseases causes kidney disorders such as diabetes mellitus and high blood pressure Hospital history and failure to receive other nephrotoxic drugs such as aminoglycosides, amphotericin B, cyclosporine, tacrolimus and furosemide, etc. Do not take other antioxidant supplements such as vitamins C and E.

**Exclusion criteria:**

History of acute kidney damage Lycopene allergy history History of injectable addiction

**Age**

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

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Outcome assessor

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Since the total sample size is 60 people, 15 blocks of 4 were defined and 6 different modes of blocks were considered. Then, by determining random numbers by computer, the order of blocks was determined and finally the process of sampling was based on the obtained sequences.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

In order to blind, none of the patients and the outcome assessor were aware of the type of group therapy received by the patients until the end of study. The treatment pills were in two groups as closed packs with codes A and B, which were assigned to group A packs containing code A and to group B packs with code B.

**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**

Isfahn University of Medical Sciences, Hezar Jarib st, Isfahan

**City**

Isfahan

**Province**

Isfahan

**Postal code**

7346181746

**Approval date**

2019-05-25, 1398/03/04

**Ethics committee reference number**

IR.MUI.MED.REC.1398.104

**Health conditions studied****1****Description of health condition studied**

Vancomycin-induced nephrotoxicity

**ICD-10 code**

N14.4

**ICD-10 code description**

Toxic nephropathy, not elsewhere classified

**Primary outcomes****1****Description**

Serum creatinine

**Timepoint**

Before starting treatment, one day between treatments and 12 hours after the last dose of vancomycin on the tenth day of treatment

**Method of measurement**

Photometric

**2****Description**

Blood urea nitrogen

**Timepoint**

Before starting treatment, one day between treatments and 12 hours after the last dose of vancomycin on the

tenth day of treatment  
**Method of measurement**  
Photometric

### 3

#### **Description**

Creatinine clearance

#### **Timepoint**

Before starting treatment, one day between treatments and 12 hours after the last dose of vancomycin on the tenth day of treatment

#### **Method of measurement**

Cockcroft-Gault formula

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention group: For people in the case group, lycopene tablets 15 mg with vancomycin will be prescribed once a day.

#### **Category**

Treatment - Drugs

### 2

#### **Description**

Control group: For control group participants, placebo tablets 15 mg with vancomycin will be prescribed once a day.

#### **Category**

Placebo

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Al-zahra hospital

##### **Full name of responsible person**

Somaye Haghighipour

##### **Street address**

Sofe Blvd, Isfahan Province, Isfahan

##### **City**

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##### **Province**

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##### **Postal code**

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##### **Phone**

+98 31 3653 1498

##### **Email**

s\_haghighipour@yahoo.com

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Esfahan University of Medical Sciences

##### **Full name of responsible person**

Shaghayegh Haghjooy Javanmard

##### **Street address**

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##### **Email**

sh\_haghjoo@med.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**

Somaye Haghighipour

##### **Position**

Associate professor

##### **Latest degree**

Specialist

##### **Other areas of specialty/work**

Infectious diseases

##### **Street address**

Alzahra hospital

##### **City**

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##### **Province**

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##### **Postal code**

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## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Esfahan University of Medical Sciences

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**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Infectious diseases

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## Person responsible for updating data

**Contact****Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

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**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Infectious diseases

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7346181746

**Phone**

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**Email**

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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**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be 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**

Undecided - It is not yet known if there will be a plan to make this available