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
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Name of organization / entity
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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
Isfehan
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

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Sofe Blvd, Isfahan Province, Isfahan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjooy Javanmard

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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

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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