Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Evaluation of the effect of curcumin in the prevention of vancomycin-induced nephrotoxicity in patients hospitalized in the intensive care unit

Protocol summary

Study aim

Evaluation of the effect of curcumin in the prevention of vancomycin-induced nephrotoxicity in patients hospitalized in the intensive care unit

Design

A phase 3, randomized, double-blind, placebo-controlled, parallel-group clinical trial of 70 patients. Eligible patients are allocated to the drug or placebo group by blocked randomization.

Settings and conduct

Setting: Intensive care units of Kosar Hospital affiliated to Semnan University of Medical Sciences and Namazi Hospital affiliated to Shiraz University of Medical Sciences. Intervention: Patients who receive vancomycin for any indication and meet the inclusion criteria, will be randomly assigned to drug or control group. The drug group will receive curcumin tablet (500 mg three times a day) and control group will receive placebo (one tablet three times a day) for 7 days started concurrently with vancomycin. Effect of intervention on renal function and urine output will be evaluated. Patient and the researcher who measures the study outcomes will be blinded until the completion of the study and the detection of its codes.

Participants/Inclusion and exclusion criteria

Patients aged 18-65; receiving vancomycin for at least 7 days; creatinine clearance > 45 ml/min; not having proteinuria and/or hematuria, acute kidney injury or any underlying renal disorder, septic shock, sever liver disease, and sever and active bleeding; not using any other nephrotoxic drug; not using antioxidant supplements; not receiving anticoagulant drugs at therapeutic doses or warfarin

Intervention groups

Patients in drug group will receive curcumin tablet (Ḏineh Iran Company), 500 mg three times a day for 7 days. Patients in control group will receive placebo (Ḏineh Iran Company) for 7 days.

Main outcome variables

Serum Creatinine; Blood Urea Nitrogen; Creatinine Clearance; 24-hour Urine Output; The Number of Cases of Acute Kidney Injury; SOFA Score

General information

Reason for update

It was changed to a two-centered study.

Acronym

IRCT registration information

IRCT registration number: **IRCT20240501061620N1**
Registration date: **2024-05-08, 1403/02/19**
Registration timing: **prospective**

Last update: **2024-10-27, 1403/08/06**
Update count: **1**

Registration date

2024-05-08, 1403/02/19

Registrant information

Name

Bahareh Hakiminia

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 23 3344 1740

Email address

baharehhakiminia@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-06-04, 1403/03/15

Expected recruitment end date

2025-09-06, 1404/06/15

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the effect of curcumin in the prevention of vancomycin-induced nephrotoxicity in patients hospitalized in the intensive care unit

Public title
Evaluation of the effect of curcumin in the prevention of vancomycin-induced nephrotoxicity in patients hospitalized in the intensive care unit
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Patients aged 18-65, receiving vancomycin Creatinine clearance > 45 ml/min
Exclusion criteria:
Proteinuria and/or hematuria, acute kidney injury or any underlying renal disorder Septic shock Sever liver disease Sever and active bleeding Receiving any other nephrotoxic drug Receiving anticoagulant drugs at therapeutic doses or receiving warfarin Receiving antioxidant supplements
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization of samples will be based on the blocked randomization method. Information such as the number of treatment groups (the two main intervention groups, drug for example, A and placebo, for example, B), the size of the blocks (a multiple of the number of groups that will be selected, in this study the size of the blocks will be 4) and the total number of patients (the sample size of 40 people) will be entered into the Internet software for this calculation (for example, available at https://www.sealedenvelope.com/simple-randomiser/v1/lists) and according to the codes with the final analysis is obtained, a code is assigned to each patient who enters the study, and the type of group that should take medication or placebo will be determined.
Blinding (investigator's opinion)
Double blinded
Blinding description
After preparation of curcumin tablets and placebo (similar to the curcumin tablet in terms of size and color), drug or placebo will be delivered in the same packaging containers by the main executor of the project who is not involved in the sampling, and the relevant code is written in each container. Patient and the researcher who measuring the study outcomes are blind to the distribution of patients in the curcumin and placebo groups until the completion of the study and the detection of its codes.
Placebo
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
Headquarter of Semnan University of Medical Sciences and Health Services, Basij Blvd
City
Semnan
Province
Semnan
Postal code
3514799442
Approval date
2024-03-11, 1402/12/21
Ethics committee reference number
IR.SEMUMS.REC.1402.317

2

Ethics committee
Name of ethics committee
Ethics Committee of Shiraz University of Medical Sciences
Street address
Headquarter of Shiraz University of Medical Sciences and Health Services, Zand Ave
City
Shiraz
Province
Fars
Postal code
7134814336
Approval date
2024-03-11, 1402/12/21
Ethics committee reference number
IR.SEMUMS.REC.1402.317

Health conditions studied

1

Description of health condition studied
Acute kidney failure
ICD-10 code
N17.9
ICD-10 code description
Acute kidney failure, unspecified

Primary outcomes

1

Description
Serum Creatinine
Timepoint
At baseline and 2, 4, 6, and 8 days after initiation of intervention
Method of measurement
Spectrophotometry

2

Description
Blood Urea Nitrogen
Timepoint
At baseline and 2, 4, 6, and 8 days after initiation of intervention
Method of measurement
Spectrophotometry

3

Description
Creatinine Clearance
Timepoint
At baseline and 2, 4, 6, and 8 days after initiation of intervention
Method of measurement
Modification of Diet in Renal Disease (MDRD) Formula

4

Description
24-hour Urine Output
Timepoint
Days 1 to 7
Method of measurement
Urine bag

5

Description
The number of patients with acute kidney injury
Timepoint
End of intervention
Method of measurement
Counting

6

Description
Sequential Organ Failure Assessment (SOFA)
Timepoint
At baseline and end of intervention
Method of measurement
SOFA table

Secondary outcomes

1

Description
Mortality rate of patients
Timepoint
After intervention until discharge from ICU
Method of measurement
Counting

2

Description
Length of stay in the ICU
Timepoint
At discharge day from ICU
Method of measurement
Counting

Intervention groups

1

Description
Intervention group: Patients will receive curcumin tablet (Dineh Iran Company), 500 mg three times a day for 7 days.
Category
Prevention

2

Description
Control group: Patients will receive placebo tablet (Dineh Iran Company) for 7 days.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Kosar Hospital
Full name of responsible person
Bahareh Hakiminia
Street address
Golestan Town, Basij Blvd
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3519899951

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2

Recruitment center

Name of recruitment center
Namazi Hospital

Full name of responsible person
Bahare Firouzbakht

Street address
Namazi Sq, Zand Ave

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Shiraz

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Fars

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7193613311

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Nemazee_inf@sums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Semnan University of Medical Sciences

Full name of responsible person
Majid Mirmohammadkhani

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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
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
Solaleh Rezanavaz Gheshlagh

Position
Student

Latest degree
A Level or less

Other areas of specialty/work
General Practitioner

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Kosar Hospital, Golestan Town, Basij Blvd

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
Bahareh Hakiminia

Position
Assistant professor

Latest degree
Specialist

Other areas of specialty/work
Medical Pharmacy

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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
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Position
Assistant professor

Latest degree
Specialist

Other areas of specialty/work
Medical Pharmacy

Street address
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3519899951

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
Confidential

Study Protocol
No - There is not 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