Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Investigating the effect of theophylline on vancomycin-induced nephrotoxicity in children aged one month to 18 years with severe infection compared to vancomycin alone.

Protocol summary

Study aim
Determining the prophylactic effect of theophylline on vancomycin-induced nephrotoxicity
Design
A clinical trial with a control group, parallel groups, blinded outcome assessment, randomized on 34 patients
Settings and conduct
In this study, which is a clinical trial and is performed in Sabzevar Heshmatieh Hospital, patients who are treated with vancomycin due to severe systemic infection including meningitis and septicemia will be selected.The patients will be one month to 18 year old. 34 patients are divided into two groups of 17 people. The permutation block method is used to allocate the samples. The method of blindness is single-blinding so that the evaluators do not know how to allocate the drug.
Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients with systemic infection treated with vancomycin Complete the informed consent form Age one month to 18 years Exclusion criteria: Patients who are discharged from the hospital before three days. Patients with unpredictable complications. Patients with drug side effects.
Intervention groups
The control group treated with vancomycin and the intervention group received theophylline every 12 hours for three days in addition to vancomycin.
Main outcome variables
1) Microalbuminuria 2) Serum urea 3) Serum creatinine

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20220326054351N1**
Registration date: **2022-08-30, 1401/06/08**
Registration timing: **registered_while_recruiting**

Last update: **2022-08-30, 1401/06/08**
Update count: **0**
Registration date
2022-08-30, 1401/06/08

Registrant information
Name
Seyyede Elahe Rahnama rahchamandi
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2022-08-23, 1401/06/01
Expected recruitment end date
2023-03-21, 1402/01/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effect of theophylline on vancomycin-induced nephrotoxicity in children aged one month to 18 years with severe infection compared to vancomycin alone.

Public title

The prophylactic effect of theophylline on vancomycin-induced nephrotoxicity

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with systemic infection treated with vancomycin Patients one month to 18 years Complete the informed consent form

Exclusion criteria:

Patients who are discharged from the hospital before three days. Patients with unpredictable complications. Patients with drug side effects.

Age

From **1 month** old to **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **34**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, all children with severe infection, including meningitis and septicemia, who are treated with vancomycin are included. In this method, we have two treatment groups, where T is considered as the group receiving theophylline and vancomycin, and C is considered as the group receiving vancomycin. Including blocks of four, we will have six modes that we use in the form of six cards with a replacement for random allocation. These six modes are as follows. TTCC, TCTC, CTTC, CTCT, TCCT, CCTT For a sample size of 34 to 9 times, we use the above cards with replacement.

Blinding (investigator's opinion)

Single blinded

Blinding description

The method of blinding is single-blinding. The researcher knows how to allocate drugs to the samples. The laboratory expert does not know how to allocate the drugs to the samples. The evaluator of laboratory results, is a person who is not aware of the treatment allocation. The outcome is evaluated objectively, so there is no necessity to blind the patient.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Sabzevar University of Medical Sciences

Street address

No. 196, Al-ahmad sq.,

City

Sabzevar

Province

Razavi Khorasan

Postal code

9617697481

Approval date

2022-01-02, 1400/10/12

Ethics committee reference number

IR.MEDSAB.REC.1400.138

Health conditions studied

1

Description of health condition studied

nephrotoxicity

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The percentage of people treated with vancomycin who develop microalbuminuria

Timepoint

Measurement of microalbuminuria at the beginning of the study and 72 hours after starting treatment with vancomycin

Method of measurement

Measurement of microalbuminuria in urine sample.The range is 30-300 mg per 24 hours.

2

Description

The percentage of people treated with vancomycin who experience an increase in urea and creatinineCommunity Verified icon

Timepoint

Measurement of urea and creatinine at the beginning of the study and 72 hours after starting vancomycin treatment

Method of measurement

Measurement of urea and creatinine in serum samples.Depending on the patients age, urea 20-30 mg/dL and creatinine 0.4-1 mg/dL.

Secondary outcomes

1

Description
Patient weight change
Timepoint
before treatment & after three days from the start of treatment
Method of measurement
Measuring the patient's weight in kilograms with a digital scale

Intervention groups

1

Description
Intervention group:Patients are treated with vancomycin and theophylline. Vancomycin is prescribed at a dose of 15 mg/kg every eight hours from the first day of hospitalization. The duration of treatment is 7-10 days.(Vancomycin 500 vial manufactured by Dana Company under the brand name Vancomax.) Depending on which form of theophylline the child is able to take, syrup or tablets are chosen. Theophylline is prescribed daily at a dose of 5 mg/kg and lasts for three days.(Theochal-G syrup made by Alborz Drug Company or theophylline tablet E.R. 200 made by Razak Laboratory Company.)
Category
Prevention

2

Description
Control group:pattients are only treated with vancomycin. Vancomycin is prescribed with dose of 15 mg/kg every eight hours from the first day of hospitalization. The duration of treatment is 7-10 days.(Vancomycin 500 vial manufactured by Dana Company under the brand name Vancomax.)
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Heshmatieh hospital, Asad-abadi ST, Sabzevar, Razavi Khorasan Province, Iran
Full name of responsible person
Aghil Keykhosravi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Sabzevar University of Medical Sciences
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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
Sabzevar 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
Sabzevar University of Medical Sciences
Full name of responsible person
Aghil Keykhosravi
Position
Associate Professor
Latest degree

Subspecialist
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All data can be anonymized after de-identifying individuals.
When the data will become available and for how long
The access period starts 6 months after the results are published
To whom data/document is available
Everyone is allowed to access the data.
Under which criteria data/document could be used
In order to reanalyze and use the data in larger scale studies conducted by other researchers.
From where data/document is obtainable
Dr.Aghil-allah Keykhosravi drakeykhosravi@yahoo.com
What processes are involved for a request to access data/document
The request should be made through the provided email
Comments