Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Aug 2026

Evaluation of magnesium sulfate efficacy in prevention of acute kidney injury induced by vancomycin+piperacillin-tazobactam combination

Protocol summary

Study aim
Evaluation of magnesium sulfate efficacy in prevention of acute kidney injury induced by vancomycin+piperacillin-tazobactam combination

Design
This is an open-label randomized clinical trial. Fifty four adults will equally be assigned to magnesium or control group according the permuted block randomization method.

Settings and conduct
Patients of intensive care units of Imam Khomeini Hospital Complex with inclusion criteria of the study will be randomly assigned to either the magnesium or the control group.

Participants/Inclusion and exclusion criteria
Patients (18-75 years old) with no history of renal failure who are candidate to receive vancomycin + piperacillin-tazobactam regimen empirically or based on microbial culture will be included.

Intervention groups
All patients will receive vancomycin + piperacillin-tazobactam. Patients in the magnesium group will receive intravenous magnesium sulfate to achieve the target serum Mg level around 3 mg/dL and this level will be maintained for 5 days. The control group will receive the same volume of normal saline. In patients in the control group, if serum magnesium level drops to less than 1.7 mg/dl at any time of the intervention course, it will be corrected toward ≥ 1.7 mg/dl.

Main outcome variables
Incidence of acute kidney injury

General information

Reason for update

Acronym
MSIVPTN

IRCT registration information
IRCT registration number: **IRCT20100228003449N26**
Registration date: **2019-10-20, 1398/07/28**
Registration timing: **registered_while_recruiting**

Last update: **2019-10-20, 1398/07/28**
Update count: **0**

Registration date
2019-10-20, 1398/07/28

Registrant information

Name
Hossein Khalili

Name of organization / entity
Tehran University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-09-23, 1398/07/01

Expected recruitment end date
2020-03-20, 1399/01/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of magnesium sulfate efficacy in prevention of acute kidney injury induced by vancomycin+piperacillin-tazobactam combination

Public title

Magnesium sulfate in prevention of vancomycin+piperacillin-tazobactam nephrotoxicity

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with age between 18-75 years Patients without history of renal failure Patients with indication to receive vancomycin+piperacillin-tazobactam

Exclusion criteria:

known history of hypersensitivity reactions to vancomycin and betalactams Pregnancy Patients with creatinine clearance less than 60 ml/min

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **54**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be done according to the blocks randomization method. Regarding to the sample size, nine blocks will be chosen. Random sequences will be created by SAS software.

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

Ethics Committee of Tehran University Of Medical Scienses

Street address

Ghods Ave. Tehran University of Medical Sciences, Tehran, Iran

City

Tehran

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Tehran

Postal code

1417614411

Approval date

2019-09-02, 1398/06/11

Ethics committee reference number

IR.TUMS.TIPS.REC.1398.080

Health conditions studied

1

Description of health condition studied

Acute Kidney Injury

ICD-10 code

N17.0

ICD-10 code description

Acute renal failure with tubular necrosis

Primary outcomes

1

Description

Incidence of acute kidney injury

Timepoint

Daily

Method of measurement

Increase in serum creatinine by 0.3 mg/dl or more than 50% from the baseline value

2

Description

Time of acute kidney injury occurrence

Timepoint

Daily

Method of measurement

Recording of incidence time

Secondary outcomes

1

Description

Length of ICU stay

Timepoint

Daily

Method of measurement

Recording of stay days

Intervention groups

1

Description

Magnesium group: This patients will receive vancomycin (15mg/kg every 8-12 hours) + piperacillin-tazobactam (4.5 g every 6 hour) concomitant with intravenous magnesium sulfate on the basis of rule of thumb (each 1g intravenous magnesium sulfate raises 0.15 mEq/l of serum magnesium) to achieve the target serum Mg level around 3 mg/dL. This level will be maintained for 5 days. Every 2 grams of magnesium sulfate will be diluted in 50 ml normal saline and will be infused over 2- hour period.

Category

Treatment - Drugs

2

Description
Control group: This patients will receive vancomycin (15mg/kg every 8-12 hours) + piperacillin-tazobactam (4.5 g every 6 hour) concomitant with the same volume of normal saline. If serum magnesium level drops to less than 1.7 mg/dl at any time of the intervention course, it will be corrected toward ≥ 1.7 mg/dl.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital Complex
Full name of responsible person
Hossein Khalili
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Hossein Khalili
Position
Professor
Latest degree
Specialist
Other areas of specialty/work
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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

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is 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

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

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

Title and more details about the data/document

Results of the study will be published. The study protocol and statistical analysis will be included in the manuscript

When the data will become available and for how long

One year after finishing the study, data will be published and will be available in databases

To whom data/document is available

After permission form the sponsor, data of the study will be available for academic researchers, physicians and scientific institutes

Under which criteria data/document could be used

Other researchers are permitted to included the results in their systematic reviews and meta-analysis

From where data/document is obtainable

For this you may ask Hossein Khalili through following information: Address: Department of Clinical Pharmacy, Faculty of Pharmacy, Tehran University of Medical Sciences, 16 Azar Ave., Tehran, Iran Postal code: 1417614411 E-mail: khalilih@tums.ac.ir

What processes are involved for a request to access data/document

After receiving the query, dependent on the requested data, the scientific responsible person of the study will response to the query in coordinate with the sponsor within 2 weeks

Comments