Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of chemoprotective effect of NAC on vancomycin induced nephrotoxicity in acute bacterial meningitis patients

Protocol summary

Summary

the main goal of this study is evaluation of chemoprotective effect of NAC on vancomycin induced nephrotoxicity in acute bacterial meningitis patients and its specific goal is evaluating saftey and efficacy of NAC on vancomycin induced nephrotoxicity. Inclusion criteria: Filling consent form Patients with diagnosis of acute bacterial meningitis who are candidated for receiving vancomycin Age≥16 yrs Not receive vancomycin in last 2weeks Exclusion criteria: Clinical states which could change phahrmacokinetic of vancomycin (eg. burn, cystic fibrosis) Pregnancy Patients with CKD who need dialysis Contraindication for vancomycin, treatment with other nephrotoxic agents. this study is a randomized controlled clinical trial which 60 patients with diagnosis of acute bacterial meningitis who have indication for recieving vancomycin included in it. They will be devided in two 30patients group, that first group will receive vancomycin with NAC(1200mg BD) and second group will receive vancomyc in 1hour infusion. all patients will be evaluated during the study for clinical response on basis of laboratory parameters (CBC & LP findings), physiologic examination at the begining of study and 5 and 10 days of treatment,10cc blood sample will be drawn from all of the patients for evaluating the level of Cystatin-C. after infusion of third dose of vancomycin and in 10th day of therapy before morning dose ,blood sample for measurement of serum trough level of vancomycin will be drawn. Serum creatinine will be checked every other days. serum level of acute kidney injury biomarker and vancomycin will be measured with standard methods.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013091814693N1**
Registration date: **2013-10-03, 1392/07/11**
Registration timing: **prospective**
Last update:
Update count: **0**

Registration date

2013-10-03, 1392/07/11

Registrant information

Name
Zahra Sahraei
Name of organization / entity
Faculty of pharmacy, Shahid beheshti university of medical sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Shahid Beheshti University of Medical Science (pharmacy faculty)

Expected recruitment start date

2013-12-22, 1392/10/01

Expected recruitment end date

2015-03-11, 1393/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of chemoprotective effect of NAC on vancomycin induced nephrotoxicity in acute bacterial meningitis patients

Public title

Chemoprotective effect of NAC on vancomycin induced

nephrotoxicity

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Filling consent form; Patients with diagnosis of acute bacterial meningitis who are candidated for receiving vancomycin; Age≥16 yrs; Not receive vancomycin in last 2weeks Exclusion criteria: Clinical states which could change phahrmacokinetic of vancomycin (eg. burn, cystic fibrosis); Pregnancy; Patients with CKD who need dialysis ; Contraindication for vancomycin, treatment with other nephrotoxic agents.

Age

From **16 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

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

Shahid Beheshti University of Medical Sciences

Street address

Vali-e Asr Ave.,Niayesh junction ,Shahid Beheshti University of Medical sciences

City

Tehran

Postal code

Approval date

2013-09-01, 1392/06/10

Ethics committee reference number

92-251

Health conditions studied

1

Description of health condition studied

acute bactrial meningitis

ICD-10 code

G00.9

ICD-10 code description

Bacterial meningitis, unspecified

Primary outcomes

1

Description

serum level of Cystatin-C

Timepoint

Baseline,5 and 10 days after treatment

Method of measurement

Turbidimetry

2

Description

serum level of vancomycin

Timepoint

Baseline,5 and 10 days after treatment

Method of measurement

immunoassay technique,mcg/ml

Secondary outcomes

1

Description

serum level of creatinine

Timepoint

every other days from begining of study

Method of measurement

jaffe method،mg/dl

Intervention groups

1

Description

that study group will receive NAC(1200mg BD) from begining of study until 10 days.

Category

Prevention

2

Description

Control group:standard regimen for treatment of meningitis

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Loghman hakim Hospital

Full name of responsible person

Dr. Shervin Shokouhi

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Faculty of Pharmacy Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr zahra Sahraei

Street address

Vali-e Asr Ave.,Niayesh junction ,Shahid Beheshti University of Medical sciences

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Faculty of Pharmacy Shahid Beheshti University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Faculty of pharmacy

Full name of responsible person

Dr Morteza Taheri

Position

Resident of clinical pharmacy

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Faculty of pharmacy,Shahid Beheshti University Of Medical Sciences

Full name of responsible person

Zahra sahraei, Azadeh Eshraghi

Position

Assistant professor,Resident of clinical pharmacy

Other areas of specialty/work

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Web page address

Person responsible for updating data

Contact

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty