Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The Effects of Administration of Vitamin E on Colistin Associated Nephrotoxicity in Treatment of Drug Resistance Gram Negative Bacterial Infections

Protocol summary

Study aim
evaluating the effect of vitamin E on colisitn associated nephrotoxicity
Design
Randomized controlled trial
Settings and conduct
Loghman-hakim hospitalized patients
Participants/Inclusion and exclusion criteria
study population consist of hospitalized patients who have bacteremia with positive blood cluture for multi-drug resistance gram negative organism which is sensitive to colisitn, Pneumonia with positive trocheal cluture for multi-drug resistance gram negative organism which is sensitive to colisitn, urinary tract infection with positive urinary cluture for multi-drug resistance gram negative organism which is sensitive to colisitn or meningitis with cerebrospinal fluid cluture for multi-drug resistance gram negative organism which is sensitive to colisitn.
Intervention groups
patients will receive vitamin E to prevent or decrease colistin associated nephrotoxicity with the dose of 400 IU/day concomitantly with colistin Patients in control group will receive colistin without receiving vitamin E during study period.
Main outcome variables
Serum creatinine ; Blood urea nitrogen ; glomerular filtration rate

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20130917014693N8**
Registration date: **2019-05-18, 1398/02/28**
Registration timing: **prospective**
Last update: **2019-05-18, 1398/02/28**
Update count: **0**
Registration date
2019-05-18, 1398/02/28

Registrant information
Name
Zahra Sahraei
Name of organization / entity
Faculty of pharmacy, Shahid beheshti university of medical sciences
Country
Iran (Islamic Republic of)
Phone
+98 21 8887 3704
Email address
z.sahraei@sbmu.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2019-05-22, 1398/03/01
Expected recruitment end date
2020-03-19, 1398/12/29
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The Effects of Administration of Vitamin E on Colistin Associated Nephrotoxicity in Treatment of Drug Resistance Gram Negative Bacterial Infections

Public title
The Effects of Administration of Vitamin E on Colistin

Associated Nephrotoxicity

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

candidate to receive colistin to treat infection with positive blood culture for multi-drug resistance gram negative organism which is sensitive to colistin pneumonia with positive tracheal culture for multi-drug resistance gram negative organism which is sensitive to colistin urinary tract infection with positive urinary culture for multi-drug resistance gram negative organism which is sensitive to colistin meningitis with positive Cerebrospinal fluid culture for multi-drug resistance gram negative organism which is sensitive to colistin receiving colistin for at least one week

Exclusion criteria:

Chronic kidney disease Acute kidney injury Receiving amphotericin B Receiving intravenous ascorbic acid Active bleeding Pregnancy Patient's death

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

The random allocation sequence will computer generate and consist of series of group number (either 1 = A or 2 = B) for each consecutive patient. Block randomization method will use and each block will be consist of 10 patients. Each block includes 5 patients who will receive Vitamin E and 5 patients from control group.

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 committe of Shahid Beheshti University of Mediacl Sciences

Street address

Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

19839-63113

Approval date

2019-01-29, 1397/11/09

Ethics committee reference number

IR.SBMU.PHARMACY.REC.1397.207

Health conditions studied

1

Description of health condition studied

colistin associated nephrotoxicity

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Serum creatinine

Timepoint

baseline then daily to the end of colistin administration

Method of measurement

blood sample

2

Description

glomerular filtration rate

Timepoint

baseline then daily to the end of colistin administration

Method of measurement

Cockcroft-Gault Formula

3

Description

Blood urea nitrogen

Timepoint

baseline then daily to the end of colistin administration

Method of measurement

blood sample

4

Description

Urinary output

Timepoint

baseline then daily to the end of colistin administration

Method of measurement

Measuring patient's urine volume

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients will receive vitamin E in (alpha tocopherol) by dose of 400 IU/day in form of four 100 IU chewable tablets which will be chew by patients or will be crushed and feed to the patient by nasogasteric tube. Vitamin E will be administered concomitantly by colistin at least for 7 days
Category
Treatment - Drugs

2

Description
Control group: Patients won't receive vitamin E concomitantly with colistin
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Loghman-hakim hospital
Full name of responsible person
Dr.Zahra Sahraei, Assitant professor of Clincal Pharmacy
Street address
Makhsoos St, South Karegar Ave, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1991953381
Phone
+98 21 5102 5000
Email
zahra.sahraei@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr Nima Naderi
Street address
Faculty of Pharmacy-Niyayesh intersection-Valiasr St
City
Tehran
Province
Tehran
Postal code
1991953381
Phone
+98 21 8820 0118
Email
zahra.sahraei@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr.Omid Moradi
Position
Clinical Pharmacy Resident
Latest degree
Medical doctor
Other areas of specialty/work
Medical Pharmacy
Street address
Niayesh Highway, Valiasr Ave, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1991953381
Phone
+98 21 8820 0118
Email
O_moradi@outlook.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr.Zahra Sahraei
Position
Assistant Professor of Clinical Pharmacy
Latest degree
Specialist
Other areas of specialty/work

Infectious diseases

Street address
Niayesh Highway, Valiasr Ave, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1991953381

Phone
+98 21 8820 0209

Email
zahra.sahraei@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Dr.Omid Moradi

Position
Clinical Pharmacy Resident

Latest degree
Medical doctor

Other areas of specialty/work
Medical Pharmacy

Street address
Niayesh Highway, Valiasr Ave, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1991953381

Phone
+98 21 8820 0118

Email
O_moradi@outlook.com

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
No - There is not a plan to make this available

Data Dictionary
Not applicable

Title and more details about the data/document
Primary outcome data after making unrecognizable will be released

When the data will become available and for how long
6 months after publishing the results primary outcome data will be released

To whom data/document is available
Researchers after allowance of corresponding author could have the permission to have the data

Under which criteria data/document could be used
Performing any analysis will be allowed only with the permission of corresponding author

From where data/document is obtainable
Corresponding author

What processes are involved for a request to access data/document
After requesting to reach data, corresponding author will check the allowance, then the researcher will be informed about it

Comments