

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jul 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 colistin 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 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 or meningitis with cerebrospinal fluid culture for multi-drug resistance gram negative organism which is sensitive to colistin.

##### 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 committee of Shahid Beheshti University of Medical 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 Clinical Pharmacy

##### Street address

Makhsos 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

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##### Province

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##### Postal code

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##### 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

O\_moradi@outlook.com

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**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

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**Postal code**

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**Phone**

+98 21 8820 0118

**Email**

**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**