Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Comparing efficacy and safety of Colistin Loading dose regimen versus Conventional regimen in improving clinical and microbiological response for the treatment of multidrug resistant gram-negative infections in pediatrics

Protocol summary

Study aim

This study was designed to prove the hypothesis that loading dose of colistin is more effective than the conventional dose in improvement of life threatening Infections in pediatrics.

Design

The study is a multi center, single blind, parallel, phase III, randomized clinical trial. The sample size is 48. Randomization was done through permuted block randomization method.

Settings and conduct

The study is scheduled to be conducted in the children medical center and Mofid hospital in Tehran

Participants/Inclusion and exclusion criteria

Inclusion criteria: age from 1 month to 18 years old; suffering from bacteremia or Ventilator associated pneumonia; a Gram-negative culture only susceptible to Colistin; Normal renal function before Colistin initiation; Colistin administered for at least 4 days. Non inclusion criteria: Parents Dissatisfaction; Receiving Nebulized form of Colistin for VAP; Receiving antibiotics effective on gram negative micro organisms other than Colistin and Meropenem.

Intervention groups

In the intervention group, first a loading dose of Colistin is given to the child and then the child go on on maintenance dose. After 72 hours of starting Colistin, patient will be evaluated for clinical and microbial responses and nephrotoxicity and neurotoxicity. In the control group, from the beginning the patient will receive maintenance dose and the rest will be like the intervention group.

Main outcome variables

Clinical response; Microbial clearance; Resistance to Colistin; Nephrotoxicity; Neurotoxicity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170614034532N2**
Registration date: **2018-06-11, 1397/03/21**
Registration timing: **prospective**

Last update: **2018-06-11, 1397/03/21**
Update count: **0**

Registration date

2018-06-11, 1397/03/21

Registrant information

Name

shiva fatehi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6690 1887

Email address

sh_fatehi@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-23, 1397/05/01

Expected recruitment end date

2019-03-20, 1397/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparing efficacy and safety of Colistin Loading dose regimen versus Conventional regimen in improving clinical and microbiological response for the treatment of multidrug resistant gram-negative infections in pediatrics

Public title
Colistin loading dose in pediatrics

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Colistin receiving for at least four days Normal baseline renal status before administration of Colistin Children from 1 month to 18 years Children with a positive blood culture or VAP Gram negative culture which is only susceptible to Colistin

Exclusion criteria:
Parents Dissatisfaction Receiving Nebulized form of Colistin for VAP Receiving antibiotics effective on gram negative micro organisms other than Colistin and Meropenem

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

Gender
Both

Phase
3

Groups that have been masked

- Participant

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
The Method for randomization in this RCT is permuted block randomization. The unit of randomization is persons. The tool for randomization is random number table.

Blinding (investigator's opinion)
Single blinded

Blinding description
In this study after Obtaining consent letter from the child's parents,the child will be randomly placed in one of the interventional or control group.Since the researcher and the physician and nurse that are responsible for the patients know that the child is receiving Colistin loading dose or not ,so the study is single blind.

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 Sciences

Street address
Faculty of Pharmacy, Tehran University of Medical Sciences, Enghelab Ave, Tehran,

City
Tehran

Province
Tehran

Postal code
1417614411

Approval date
2017-06-25, 1396/04/04

Ethics committee reference number
1396.2744

Health conditions studied

1

Description of health condition studied
bloodstream infections

ICD-10 code

ICD-10 code description

2

Description of health condition studied
Ventilator Associated Pneumonia

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Clinical response

Timepoint
at the beginning of the study (before starting the intervention) and 72 hours after the start of treatment

Method of measurement
Laboratory data

2

Description
Microbiological response

Timepoint
at the beginning of the study (before starting the intervention) and 72 hours after the start of treatment

Method of measurement
Microbial culture

Secondary outcomes

1

Description
The prevalence and severity of Nephrotoxicity
Timepoint
72hrs after starting Colistin
Method of measurement
Laboratory data; Measurement of Urine Volume

2

Description
The prevalence of Neurotoxicity
Timepoint
72hrs after starting Colistin
Method of measurement
Clinical outcomes

3

Description
The prevalence of Colistin resistance
Timepoint
72hrs after starting Colistin
Method of measurement
Microbial culture

Intervention groups

1

Description
Intervention group: Patients receive a loading dose of 150,000 IU/Kg.The loading dose is followed by 50,000 IU every 8 hours. Clinical, microbiological and laboratory findings are collected for each patient on 1th and 4th day after treatment.The Nephrotoxicity is assessed based on PRIFLE recommendation on day 4 after treatment.
Category
Treatment - Drugs

2

Description
Control group:Patients receive Colistin at the dose of 50,000 IU every 8 hours. Clinical, microbiological and laboratory findings are collected for each patient on 1th and 4th day after treatment.The Nephrotoxicity is assessed based on PRIFLE recommendation on day 4 after treatment.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Children medical center
Full name of responsible person
Shiva Fatehi
Street address
Dr.Qarib Street,Keshavarz Blvd
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Tehran
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2

Recruitment center
Name of recruitment center
Mofid hospital
Full name of responsible person
Bahador Mirrahimi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mohammad Ali Sahraeian
Street address
6th floor,central university building,Quds Street,Keshavarz Blvd
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No

Title of funding source
دانشگاه علوم پزشکی تهران
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
Shiva Fatehi
Position
Resident of Clinical pharmacy
Latest degree
Medical doctor
Other areas of specialty/work
Clinical pharmacist
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no more innformation
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available