Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Evaluation of the Effect of Oral fosfomycin Addition on Treatment of Patients with Klebsiella pneumoniae Carbapnemase Infections with Colistin

Protocol summary

Study aim

Evaluation of the Effect of Oral Phosphomycin Addition on Treatment of Patients with Klebsiella pneumoniae Carbapnemase Infections with Colistin

Design

A clinical trial study in which patients with Klebsiella pneumoniae carbapenemase infection diagnosed by reliable culture and admitted to the infectious ward of Vali Asr Hospital are included. In this study 62 patients were randomly divided into fosfomycin + cholestine and cholestine groups.The trial phase is 3

Settings and conduct

A clinical trial study in which patients with Klebsiella pneumoniae carbapenemase infection diagnosed by reliable culture and admitted to the infectious ward of Vali Asr Hospital are included. In this study 62 patients were randomly divided into fosfomycin + cholestine and cholestine groups .The study is open label

Participants/Inclusion and exclusion criteria

Patients with Klebsiella Pneumoniae Carbapenemase infection diagnosed by reliable culture and admitted to the infectious ward of Vali Asr Hospital are studied.Exclusion criteria included : Allergy to fosfomycin- Patients with renal failure - Hemodialysis Patients - Under 12 years age- Patients who have received antibiotics affecting KPC for the past 72 hours.

Intervention groups

Intervention group: In the first 7 days of treatment, 31 patients will receive colistin (3 million units of TDS injectable colistin) along with oral fosfomycin (3 g per 12-hour dose). The total duration of treatment is 14 days.

Main outcome variables

Leukocytosis - mute the fever -Symptoms Remedy - Negative urine culture

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191104045328N1**
Registration date: **2019-11-10, 1398/08/19**
Registration timing: **prospective**

Last update: **2019-11-10, 1398/08/19**
Update count: **0**

Registration date

2019-11-10, 1398/08/19

Registrant information

Name

Amin Haji seyyed hoseini

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 86 3366 7583

Email address

amin.medstu@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-11, 1398/09/20

Expected recruitment end date

2020-11-10, 1399/08/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Evaluation of the Effect of Oral fosfomycin Addition on Treatment of Patients with Klebsiella pneumoniae Carbapnemase Infections with Colistin

Public title
Evaluation of the Effect of Oral fosfomycin Addition on Treatment of Patients with Klebsiella pneumoniae Carbapnemase Infections with Colistin

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with Klebsiella Pneumoniae Carbapenemase infection diagnosed by reliable culture and admitted to the infectious ward of Vali Asr Hospital are studied.

Exclusion criteria:
Allergy to fosfomycin Patients with renal failure Hemodialysis Patients Under 12 years age Patients who have received antibiotics affecting KPC for the past 72 hours.

Age
From **12 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **62**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization with Random Number Table

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 Arak University of Medical Sciences

Street address
Research Assistant, Arak University of Medical Sciences, Basij Square, Sardasht, Arak, Iran

City
Arak

Province
Markazi

Postal code
3814957558

Approval date
2019-09-29, 1398/07/07

Ethics committee reference number
IR.ARAKMU.REC.1398.191

Health conditions studied

1

Description of health condition studied
Klebsiella pneumoniae Carbapnemase Infections

ICD-10 code
B96.1

ICD-10 code description
Klebsiella pneumoniae [K. pneumoniae] as the cause of diseases classified elsewhere

Primary outcomes

1

Description
Leukocytosis

Timepoint
After a week of treatment

Method of measurement
Blood cell count

2

Description
mute the fever

Timepoint
24 hours / 48 hours / 72 hours / 96 hours / over 96 hours from start of treatment

Method of measurement
Using mercury thermometer orally or axillary

3

Description
Symptoms Remedy

Timepoint
24 hours / 48 hours / 72 hours / 96 hours / over 96 hours from start of treatment

Method of measurement
Asking about the patient and the patient's status by observation

4

Description
Negative urine culture

Timepoint
After 72 hours of treatment

Method of measurement
urine culture test

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In the first 7 days of treatment, 31 patients will receive colistin (3 million units of TDS injectable colistin) along with oral fosfomycin (3 g per 12-hour dose). The total duration of treatment is 14 days.
Category
Treatment - Drugs

2

Description
Control group: 31 patients will receive colistin for a total of 14 days (3 million units of TDS injectable colistin)
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Vali Asr hospital
Full name of responsible person
Dr hosein sarmadian
Street address
Valiasr Hospital,Shahid Shiroudi Street, Arak, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Dr Mohammad Arjmandzadegan
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Research Assistant, Arak University of Medical Sciences, Basij Square, Sardasht, Arak, Iran
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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
Arak 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
Arak University of Medical Sciences
Full name of responsible person
Dr hosein sarmadian
Position
Associate Professor
Latest degree
Specialist
Other areas of specialty/work
Infectious diseases
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Person responsible for scientific inquiries

Contact
Name of organization / entity

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Full name of responsible person
Dr ehsanollah ghznavi rad

Position
Associate professor

Latest degree
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Microbiology

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Person responsible for updating data

Contact

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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
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
When the article was out of print.

When the data will become available and for how long
After publishing the article

To whom data/document is available
University researchers

Under which criteria data/document could be used
If there are any further questions

From where data/document is obtainable
Dr hosein samadian

What processes are involved for a request to access data/document
Letter writing should be done with professors and universities.

Comments