

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

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

Protocol summary

Study aim

Evaluation of the Effect of Oral Phosphomycin Addition on Treatment of Patients with Klebsiella pneumoniae Carbapenemase 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 seyed hoseini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+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

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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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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

Arak University of Medical Sciences
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Position
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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