

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of continuous infusion of Meropenem antibiotic in Clinical symptoms and Procalcitonin changes in sever sepsis

Protocol summary

Registration timing: **registered_while_recruiting**

Study aim

The effect of continuous infusion of Meropenem antibiotic in Clinical symptoms and Procalcitonin changes in sever sepsis

Last update: **2018-01-31, 1396/11/11**

Update count: **0**

Registration date

2018-01-31, 1396/11/11

Design

This study is clinical trials and double blind.60 patients admitted to the intensive care unit of Valiasr Hospital in Arak were enrolled.

Registrant information

Name

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Name of organization / entity

Arak University of Medical Sciences

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Settings and conduct

60 patients admitted to the intensive care unit of Valiasr hospital in Arak were enrolled.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 18-75 years; patients admitted to ICU with the diagnosis of evidence of infection and at least two of the symptoms of SIRS (sepsis) Exclusion criteria: Incidence of drug-related complications; no response to treatment within 72 hours

Recruitment status

Recruitment complete

Funding source

Intervention groups

Immediately after the initial diagnosis patients in the intervention group (30), one gram of moropenem in one bolus and 100 milligram in hours of antibiotic maroponum, receive continuous infusion over a period of 72 hours.Placebo is injected every 12 hours as bolus.Patients in the control group (n = 30) received one gram of moropenum as bolus dosing every 12 hours and 10 cc per hour of normal saline for continuous infusion over a period of 72 hours.

Expected recruitment start date

2017-05-20, 1396/02/30

Expected recruitment end date

2019-05-20, 1398/02/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Main outcome variables

The effect of continuous infusion of Meropenem antibiotic in Clinical symptoms and Procalcitonin changes in sever sepsis

Scientific title

The effect of continuous infusion of Meropenem antibiotic in Clinical symptoms and Procalcitonin changes in sever sepsis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141209020258N65**

Registration date: **2018-01-31, 1396/11/11**

Public title

The effect of continuous infusion of Meropenem antibiotic

in Clinical symptoms and Procalcitonin changes in sever sepsis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

18-75 years Patients admitted to ICU with the diagnosis of evidence of infection and at least two of the symptoms of SIRS (sepsis)

Exclusion criteria:

Incidence of drug-related complications No response to treatment within 72 hours

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization with random numbers

Blinding (investigator's opinion)

Double blinded

Blinding description

The patient is not aware of the treatment received. Participant and Analyzer are blind (double blind).

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee Arak University Of Medical Sciences

Street address

Vice chancellor for research, Payambar azam complex, Basij square, Sardasht, Arak

City

Arak

Province

Markazi

Postal code

3814957558

Approval date

2017-05-01, 1396/02/11

Ethics committee reference number

IR.ARAK.MU.REC.1396.2

Health conditions studied

1

Description of health condition studied

Acute sepsis

ICD-10 code

A40.9

ICD-10 code description

Streptococcal sepsis, unspecified

Primary outcomes

1

Description

Changes in Procalcitonin

Timepoint

Before and 2 weeks after treatment

Method of measurement

milligram

2

Description

GFR

Timepoint

Before and 2 weeks after treatment

Method of measurement

count

3

Description

Level of consciousness

Timepoint

At the time of arrival, 24, 48 and 72 hours after receiving the drug

Method of measurement

Glasgow scale

4

Description

Incidence of mortality

Timepoint

Before and 2 weeks after treatment

Method of measurement

Number

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: En Immediately after the initial diagnosis patients in the intervention group (30), one gram of moropenem in one bolus and 100 milligram in hours of antibiotic maroponum, receive continuous infusion over a period of 72 hours. Placebo is injected every 12 hours as bolus

Category

Treatment - Drugs

2

Description

Control group: Patients in the control group (n = 30) received one gram of moropenem as bolus dosing every 12 hours and 10 cc per hour of normal saline for continuous infusion over a period of 72 .

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr hospital

Full name of responsible person

Dr Behnam Mahmodie

Street address

Valiasr Hospital, Valiasr squire, Shahid Shirodi street

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mahmodie@arakmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

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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 Alireza Kamali

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

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Person responsible for updating data

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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 we publish article in journal.

When the data will become available and for how long

After the article is published

To whom data/document is available

researcher in university

Under which criteria data/document could be used

If there are additional questions

From where data/document is obtainable

Dr Behnam mahmodie

What processes are involved for a request to access data/document

They have to write letters to the professors and the university

Comments