

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jul 2026

The evaluation of clinical and laboratory efficacy of four-hour infusion vs. half-hour infusion of Ampicillin-Sulbactam in empiric and definite treatment of patients with sepsis and severe sepsis in the intensive care unit of Namazee and shahid Rajaei hospital in Shiraz.

Protocol summary

Study aim

The evaluation of clinical and laboratory efficacy of four-hour infusion vs. half-hour infusion of Ampicillin-Sulbactam in empiric and definite treatment of patients with sepsis and severe sepsis in the intensive care unit (ICU)

Design

Pragmatic, community based, parallel group, double blind, randomised controlled trial

Settings and conduct

This study will be conducted in the ICU of Namazee and Rajaei hospital, Shiraz, Iran. The patients with sepsis and severe sepsis will be categorized into two groups by permuted block randomization: 1. Receiving Ampicillin-Sulbactam as a 0.5 hour infusion 2- Receiving Ampicillin-Sulbactam as a 4 hour infusion. Every patient will be determined by a number and the list of numbers of patients in each group will be given to the nurses. The participants, the physicians, the investigator and the data collectors will be blinded to the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: More than 18 years old; Diagnosis of sepsis and severe sepsis based on qSOFA criteria; Taking Ampicillin- Sulbactam at least for three days; Exclusion criteria: Pregnancy; Sensitivity to Ampicillin- Sulbactam; Receiving Ampicillin- Sulbactam more than 24 hours during 1 week before being admitted to the intensive care unit; Patients with GFR<10 ml/min or hemodialysis ; Patients with Pseudomonas, penicillin-resistant staph aureus (MRSA), or stenotrophomonas;

Intervention groups

- The patients with sepsis and severe sepsis receiving Ampicillin-Sulbactam as 4 hour infusion - The patients with sepsis and severe sepsis receiving Ampicillin-Sulbactam as 0.5 hour infusion

Main outcome variables

Clinical cure (resolution of signs and symptoms related to the infection, including hypothermia or hyperthermia, low platelet count, high heart rate, high respiratory rate or low PaCO₂, abnormal white blood cell count and positive microbial culture

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190425043368N1**

Registration date: **2019-06-02, 1398/03/12**

Registration timing: **registered_while_recruiting**

Last update: **2019-06-02, 1398/03/12**

Update count: **0**

Registration date

2019-06-02, 1398/03/12

Registrant information

Name

Mahtabalsadat Mirjalili

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-22, 1398/03/01

Expected recruitment end date

2020-09-21, 1399/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The evaluation of clinical and laboratory efficacy of four-hour infusion vs. half-hour infusion of Ampicillin-Sulbactam in empiric and definite treatment of patients with sepsis and severe sepsis in the intensive care unit of Namazee and shahid Rajaee hospital in Shiraz.

Public title

The comparison between short and long infusion of Ampicillin-Sulbactam in patients with sepsis and severe sepsis in the intensive care unit of Namazee and shahid Rajaee hospital in Shiraz.

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

More than 18 years old Diagnosis of sepsis and severe sepsis based on qSOFA criteria Taking Ampicillin-Sulbactam at least for three days

Exclusion criteria:

Pregnancy Sensitivity to Ampicillin- Sulbactam Receiving Ampicillin- Sulbactam more than 24 hours during 1 week before being admitted to the intensive care unit Patients with GFR<10 ml/min or hemodialysis Patients with Pseudomonas, penicillin-resistant staph aureus (MRSA), or stenotrophomonas

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **136**

Randomization (investigator's opinion)

Randomized

Randomization description

Method of randomization: Permuted block randomization. Unit of randomization: Individual. Tools used in randomization: computer software.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, the participants, the principle investigator, the physicians and the data collectors are blinded. The patients who are going to receive the drug as short or long infusion, are determined by numbers and these numbers are given to the head nurse and nurses of the ICU.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Shiraz University of Medical Sciences

Street address

School of Pharmacy, Shiraz-Marvdasht Highway, Rokn Abad Town

City

Shiraz

Province

Fars

Postal code

71468 64685

Approval date

2019-03-10, 1397/12/19

Ethics committee reference number

IR.SUMS.REC.1398.232

Health conditions studied**1****Description of health condition studied**

Severe Sepsis

ICD-10 code

R65.2

ICD-10 code description

Severe sepsis

2**Description of health condition studied**

Sepsis

ICD-10 code

A41.9

ICD-10 code description

Sepsis, unspecified organism

Primary outcomes**1****Description**

Clinical cure (resolution of signs and symptoms related to the infection, including hypothermia or hyperthermia, low platelet count, high heart rate, high respiratory rate or low PaCO₂, abnormal white blood cell count and positive microbial culture

Timepoint

At the end of therapy and 14 days after cessation of antibiotic

Method of measurement

Individual examination, measuring temperature by thermometer, complete blood count and determination of platelet and white blood cell count, measurement of heart rate and respiratory rate, analysis of blood gases, microbial culture

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Receiving Ampicillin-Sulbactam as a 4-hour infusion Patients receive 9 grams Ampicillin-Sulbactam every 8 hours, which is the therapeutic dose for resistant pathogens (3 Ampicillin-Sulbactam 3 gram vials every 8 hours, Jaber ebne hayyan pharmaceutical co). Infusion pumps will be used to determine the exact time of infusion. All the patients will receive this drug for at least 3 days. The decision to continue or stop drug is based on the microbial culture results and the patient's condition.

Category

Treatment - Drugs

2**Description**

Control group: Receiving Ampicillin-Sulbactam as a 0.5-hour infusion Patients receive 9 grams Ampicillin-Sulbactam every 8 hours, which is the therapeutic dose for resistant pathogens (3 Ampicillin-Sulbactam 3 gram vials every 8 hours, Jaber ebne hayyan pharmaceutical co). The drug is administered as the routine protocol which is 0.5-hour infusion. All the patients will receive this drug for at least 3 days. The decision to continue or stop drug is based on the microbial culture results and the patient's condition.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Namazi hospital

Full name of responsible person

Afsaneh Vazin

Street address

Shiraz school of pharmacy, Karafarin street,
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2**Recruitment center****Name of recruitment center**

Rajaei hospital

Full name of responsible person

Afsaneh Vazin

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Dr Younes Ghasemi

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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

Shiraz 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

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Person responsible for general inquiries**Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Mahtabalsadat Mirjalili

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Clinical pharmacy

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Latest degree

Medical doctor

Other areas of specialty/work

Medical Pharmacy

Street address

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Shiraz

Province

Fars

Postal code**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available