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 Rajaee 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 Rajaee 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 nvestigator 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)

Phone

+98 71 3229 3845

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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 $PaCO_2$, 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, Roknabad Town
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Postal code
713451583
Phone
+98 71 3242 4127
Email
Vazeena@sums.ac.ir

2

Recruitment center
Name of recruitment center
Rajaee hospital
Full name of responsible person
Afsaneh Vazin
Street address
Shiraz school of pharmacy, Karafarin street, Roknabad Town
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Phone
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Email
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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
Street address
Shiraz University of Medical Sciences, Zand Blvd.
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Postal code
71345-1978
Phone
+98 71 3235 7282
Email
vcrdep@sums.ac.ir
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

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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Medical doctor
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Person responsible for updating data

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Medical doctor
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mahtab.mirjalili@gmail.com

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