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 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 temperature, high respiratory rate or low PaCO2, abnormal white blood cell count and positive microbial culture

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 

Blinding (investigator's opinion) 
Double blindered
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, Roknabad Town
City
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Province
Fars
Postal code
713451583
Phone
+98 71 3242 4127
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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Shiraz school of pharmacy, Karafarin street, Roknabad Town
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Person responsible for scientific inquiries

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Full name of responsible person
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Position
Resident
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Medical doctor
Other areas of specialty/work
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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