Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparative study of the effect of ampicillin and cefotaxime antibiotics with ampicillin and amikacin in the treatment of early neonatal sepsis

Protocol summary

Study aim

Comparison of the effect of ampicillin and cefotaxime antibiotics with ampicillin and amicacin in the treatment of early neonatal sepsis

Design

This is a parallel randomized controlled clinical trial that will be performed on 94 infants with early sepsis. Randomization in this research is done using quadri blocks using syntax written in SPSS program. The duration of the study will be 3 months.

Settings and conduct

This study is a clinical trial study with a control group that will be performed on a total of 94 infants referred to Bahar Shahroud Hospital. Patients' parents must sign an informed consent form before entering the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria:Infants with early sepsis in the first 7 days of life; existence of respiratory distress, acute respiratory distress syndrome; urinary output less than 0.5 cc / kg / hr; metabolic acidosis ; cardiovascular instability; decreased infant reflexes; severe cyanosis; frequent or prolonged seizures; Increase in body temperature to more than 38.5 or less than 36 ° C axillary; apnea; Severe abdominal distension and informed consent of parents to participate in the research. Exclusion criteria: infants with major congenital anomalies; severe prematurity and less than 28 weeks; very low birth weight; congenital heart disease; severe asphyxia (Apgar 5 minutes less than 5).

Intervention groups

Patients included in the study will be divided into intervention and control groups. In the intervention group, treatment with ampicillin and cefotaxime antibiotics will be performed. In the control group, treatment with ampicillin and amikacin antibiotics will be performed.

Main outcome variables

Duration of making CRP marker negative; Need for intubation and mechanical ventilarion; Metabolic acidosis; duration of hospitalization and mortality rate.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100102002954N22**
Registration date: **2020-11-21, 1399/09/01**
Registration timing: **registered_while_recruiting**

Last update: **2020-11-21, 1399/09/01**
Update count: **0**

Registration date

2020-11-21, 1399/09/01

Registrant information

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-11-20, 1399/08/30

Expected recruitment end date

2021-01-18, 1399/10/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparative study of the effect of ampicillin and cefotaxime antibiotics with ampicillin and amikacin in the treatment of early neonatal sepsis

Public title
Comparison of the effect of ampicillin and cefotaxime with ampicillin and amikacin in the treatment of neonatal sepsis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Infants with early sepsis in the first 7 days of life; Existence of respiratory distress, hypoxia or symptoms of acute respiratory distress syndrome; Poor perfusion or urinary output less than 0.5 cc / kg / hr; Metabolic acidosis with pH <7.2; Cardiovascular instability with a heart rate of less than 160 beats per minute; Decreased infant reflexes; Severe cyanosis; Frequent or prolonged seizures; Increase in body temperature to more than 38.5 or less than 36 ° C axillary; Apnea; Severe abdominal distension; And informed consent of parents to participate in the research.

Exclusion criteria:
Infants with major congenital anomalies; Severe prematurity and less than 28 weeks; Very low birth weight (less than 1500 g); Congenital heart disease; Severe asphyxia (Apgar 5 minutes less than 5);

Age
From **1 day** old to **7 days** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **94**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be allocated into intervention and control groups according to random allocation table that illustrated by a statistician. Randomization will be done using permuted block randomization method (Block size of 4) using blocked random allocation syntax in SPSS software. Sample size will be 94 and number of blocks will be 24. Allocation concealment will be done using closed opaque envelope.

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 Shahroud University of Medical Sciences

Street address
Shahroud University of Medical Sciences; 7 Tir squer, Shahroud

City
Shahroud

Province
Semnan

Postal code
3616647555

Approval date
2020-10-25, 1399/08/04

Ethics committee reference number
IR.SHMU.REC.1399.111

Health conditions studied

1

Description of health condition studied
Early neonatal sepsis

ICD-10 code
A41

ICD-10 code description
Other sepsis

Primary outcomes

1

Description
Duration of making CRP marker negative

Timepoint
At the beginning and during the study

Method of measurement
laboratory tests

2

Description
Need for intubation and mechanical ventilarion

Timepoint
During the study

Method of measurement
Checking patient records

3

Description
Metabolic acidosis

Timepoint

During the study

Method of measurement

Laboratory test (ABG)

Secondary outcomes

1

Description

Duration of hospitalization

Timepoint

At the end of the study

Method of measurement

The time between the time / date of hospitalization and the time / date of discharge from the hospital, expressed in hours.

2

Description

Mortality rate

Timepoint

At the end of the study

Method of measurement

Mortality rate refers to the number of deaths among these infants, expressed as a percentage.

Intervention groups

1

Description

Intervention group: After initial and routine procedures including NICU admission, serum therapy and oxygen therapy, and stabilization of vital signs, ampicillin 50 mg / kg with cefotaxime 50 mg / kg will be given intravenously every 12 hours.

Category

Treatment - Drugs

2

Description

Control group: In the control group, as in the intervention group, while performing initial and routine procedures including hospitalization in the NICU, serum therapy and oxygen therapy and stabilization of vital signs, ampicillin 50 mg / kg with amikacin 7.5 mg / kg will be administered intravenously every 12 hours.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Bahar Hospital of Shahroud

Full name of responsible person

Dr. Mahboobeh Mohammadi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahroud 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?

No

Title of funding source

Vice chancellor for research; Shahroud University medical and 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
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General Practitioner
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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
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available