

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 amikacin 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 ventilation; 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

Name

Mohammad Bagher Sohrabi

Name of organization / entity

Shahroud University of Medical Sciences and Health

Country

Iran (Islamic Republic of)

Phone

+98 23 3239 5054

Email address

mb.sohrabi@shmu.ac.ir

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 ventilatorion

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

Street address

Bahar Hospital., End 22 Bahman street., Shahroud , Iran

City

Shahroud

Province

Semnan

Postal code

3616633255

Phone

+98 23 3224 5376

Fax

+98 23 3233 3902

Email

m_m361kord@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahroud University of Medical Sciences

Full name of responsible person

Dr. Mohammad Hasan Emamian

Street address

Vice chancellor for research; Shahroud University medical Sciences ,7th Tir squar, Shahroud

City

Shahroud

Province

Semnan

Postal code

3616647555

Phone

+98 23 3239 4499

Fax

+98 23 3239 4800

Email

pajouhesh@shmu.ac.ir

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

Shahroud University of Medical Sciences

Full name of responsible person

Dr. Mahya Esmaili

Position

General Practitioner

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

Street address

Bahar Hospital, End 22 Bahman street, Shahroud, Iran.

City

Shahroud

Province

Semnan

Postal code

3616633525

Phone

+98 23 3224 5376

Email

mahya.me.esmaili@gmail.com

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

Shahroud University of Medical Sciences

Full name of responsible person

Dr. Mahboobeh Mohammadi

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Neonatology

Street address

Bahar hospital., End 22 Bahman street., Shahroud., Iran

City

Shahroud

Province

Semnan

Postal code

3616622355

Phone

+98 23 3224 7653

Fax

+98 23 3233 3902

Email

m_m361kord@yahoo.com

Person responsible for updating data**Contact****Name of organization / entity**

Shahroud University of Medical Sciences

Full name of responsible person

Dr.Mohammad Bagher Sohrabi

Position

General Practitioner

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

Street address

Imam Hossein Hospital, End Imam street, Shahroud, Iran

City

Shahroud

Province

Semnan

Postal code

3616611151

Phone

+98 23 3234 2000

Fax

+98 23 3233 3902

Email

mb.sohrabi@yahoo.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

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