

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Once daily dose of Amikacin versus twice daily dose for treatment of early onset neonatal sepsis

Protocol summary

Summary

The purpose of this randomized study is using once daily dose of Amikacin versus twice dose daily for treatment of early onset neonatal sepsis. Inclusion criteria: Term Infants with the clinical signs of sepsis in premature newborn infants admitted Bou Ali Sina Hospital of Sari treated with Ampicillin plus Amikacin. Exclusion criteria : fetal age more than 42 Weeks and less than 37 weeks; Low birth weight; having congenital heart disease and asphyxia; not treated with Ampicillin and Amikacin at the age of 7 days; renal and hearing congenital disorders; prescription medications that have toxic effect on renal and auditory systems; neonatal meningitis; pathologic icter and TORCH Infections. Study sample size is 32 patients. Primary outcome: the treatment of SDL peak in therapeutic range and the treatment of through SDL in non-toxic range, 60 minutes after intramuscular administration or 30 minutes after intravenous administration in the range 15 -30mcg/ml. Control group: Treated with Amikacin twice dose of 10 mg/ kg Body weight daily that is within one hour intravenous Infusion. Case groups: treated with amikacin one Dose of 15 mg /kg body weight that is within one hour intravenous infusion.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201112248507N1**
Registration date: **2012-01-10, 1390/10/20**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-01-10, 1390/10/20

Registrant information

Name

Mohammad Sadegh Rezai

Name of organization / entity

Mazandaran University of Medical Sciences

Country

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Email address

rezai@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mazandaran University of Medical Sciences

Expected recruitment start date

2011-01-21, 1389/11/01

Expected recruitment end date

2013-01-09, 1391/10/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Once daily dose of Amikacin versus twice daily dose for treatment of early onset neonatal sepsis

Public title

Once daily dose of Amikacin versus twice daily dose for treatment of early onset neonatal sepsis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Term Infants with the clinical signs of sepsis in premature newborn infants admitted Bou Ali Sina Hospital of Sari treated with Ampicillin plus Amikacin. Exclusion criteria : fetal age more than 42

Weeks and less than 37 weeks; Low birth weight; having congenital heart disease and asphyxia; not treated with Ampicillin and Amikacin at the age of 7 days; renal and hearing congenital disorders; prescription medications that have toxic effect on renal and auditory systems; neonatal meningitis; pathologic icter and TORCH Infections.

Age

To **1 year** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **32**

Randomization (investigator's opinion)

Randomized

Randomization description**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**

Mazandaran University of Medical Sciences

Street address

NO.2 Building of University, Moallem Square

City

Sari

Postal code**Approval date**

2011-01-19, 1389/10/29

Ethics committee reference number

147-89

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

Neonatal sepsis

ICD-10 code

P36

ICD-10 code description

P36.8

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

The treatment of SDL peak in therapeutic range

Timepoint

Sixty minutes after intramuscular administration or 30 minutes after intravenous administration in the range 15-30

Method of measurement

Serum samples

2**Description**

The treatment of through SDL in non-toxic range

Timepoint

Sixty minutes after intramuscular administration or 30 minutes after intravenous administration in the range 15-30

Method of measurement

Serum samples

Secondary outcomes**1****Description**

Potential renal side effects

Timepoint

Before the next dose

Method of measurement

Serum samples

2**Description**

Potential hearing side effects

Timepoint

Before the Next Dose

Method of measurement

Auditory brainstem response and audiometry

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

Control group: treated with Amikacin twice dose of 10 mg/ kg body weight daily that is within one hour intravenous infusion.

Category

Treatment - Drugs

2**Description**

Case group: treated with amikacin one dose of 15 mg /kg body weight that is within one hour intravenous infusion.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Boali Hospital of Sari

Full name of responsible person

Dr Mohammadsadegh Rezai

Street address

City

Sari

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Dr Ahmadali Enayati

Street address

NO.2 Building of University, Moallem Square

City

Sari

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Mazandaran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Dr Mohammadsadegh Rezai

Position

Associate Professor

Other areas of specialty/work

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty