Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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
Iran (Islamic Republic of)
Phone
+98 11 3334 2334
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
Street address
Boali Hospital,Pasdaran Blv
City
Sari
Postal code
Phone
+98 15 1325 7230
Fax
+98 15 1326 1244
Email
rezai@mazums.ac.irdrmsrezaii@yahoo.com
Web page address

Person responsible for scientific 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
Street address
Boali Hospital,Pasdaran Blv.
City
Sari
Postal code
Phone
+98 15 1325 7230
Fax
+98 15 1326 1244
Email
rezai@mazums.ac.irdrmsrezaii@yahoo.com
Web page address

Person responsible for updating data

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
Street address
City
Sari
Postal code
Phone
+98 15 1325 7230
Fax
+98 15 1326 1244
Email
drmsrezaii@yahoo.comrezai@mazums.ac.ir
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