Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Jul 2026

Study of the difference of renal complications in single and double daily dose of Amikacin in patients with neonatal sepsis in Imam Khomeini Hospital in Tehran: A double blind clinical trial

Protocol summary

Study aim
The evaluation of the difference of renal complications in single and double daily dose of Amikacin in patients with neonatal sepsis in Imam Khomeini Hospital in Tehran

Design
Clinical trial of two parallel groups, without control group, double-blind, randomized, phase 3, on 90 patients, block randomization with 2 alleles and 4 sizes

Settings and conduct
This study was performed in Imam Khomeini Hospital in Tehran during one year (July 2018 to July 2019). After block randomization and bilateral blinding, the first group received 15 mg / kg amikacin daily and the second group received 10 mg / kg twice daily. Before and after seven days of treatment, the following indicators were determined and compared in two groups: GFR, serum creatinine level, creatinine clearance, FEMg.

Participants/Inclusion and exclusion criteria
Infants with sepsis without asphyxia and congenital renal anomalies

Intervention groups
the first group received 15 mg/kg Amikacin daily and the second group received 10 mg/kg twice daily

Main outcome variables
Renal complications

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20201212049686N1**
Registration date: **2021-01-18, 1399/10/29**
Registration timing: **retrospective**

Last update: **2021-01-18, 1399/10/29**
Update count: **0**

Registration date
2021-01-18, 1399/10/29

Registrant information

Name
Mojtaba Fazel

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 6119 2240

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-06-05, 1398/03/15

Expected recruitment end date
2020-06-04, 1399/03/15

Actual recruitment start date
2019-07-13, 1398/04/22

Actual recruitment end date
2020-07-08, 1399/04/18

Trial completion date
2020-10-16, 1399/07/25

Scientific title
Study of the difference of renal complications in single and double daily dose of Amikacin in patients with neonatal sepsis in Imam Khomeini Hospital in Tehran: A double blind clinical trial

Public title
Renal complications of Amikacin in patients with neonatal sepsis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

patients with neonatal sepsis Parental consent to participate in the study

Exclusion criteria:

incomplete treatment parental dissatisfaction with continuing treatment evidence of asphyxia renal abnormalities at birth

Age

From **3 days** old to **1 month** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **90**

Actual sample size reached: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients were randomly divided into two groups using block randomization. The number of samples assigned to each of the study groups and the size of the blocks were equal. Random allocation concealment was performed using Excel random number table and from the beginning of sampling, neonates with sepsis were coded according to the date of admission and were placed in each of the two groups according to random numbers.

Blinding (investigator's opinion)

Double blinded

Blinding description

The patient, who was a newborn, did not know which group he was in, and the clinical caregiver and the researcher were blinded to the dose of the drug and the assignment of each patient to each group. The data analyzer and outcome assessor were also unaware of patient grouping.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

Gharib St., Keshavarz Blvd.

City

Tehran

Province

Tehran

Postal code

1419733134

Approval date

2018-04-18, 1397/01/29

Ethics committee reference number

IR.TUMS.IKHC.REC.1397.014

Health conditions studied

1

Description of health condition studied

neonatal Sepsis

ICD-10 code

D50-D89

ICD-10 code description

Diseases of the blood and blood-forming organs and certain disorders involving the immune mechanism

Primary outcomes

1

Description

GFR above 30%

Timepoint

Before and after seven days of treatment

Method of measurement

First, serum creatinine level was measured and GFR was calculated using the Schwartz formula: Creatinine clearance in millimeters per minute per 1/73 square meter of body surface =height in cm * K/ serum creatinine (in this formula: K in premature infants up to one year of age 0.33%, in infants Semester up to one year is 0.45%)

Secondary outcomes

1

Description

Creatinine clearance

Timepoint

before one one week after Amikacin administration

Method of measurement

First, serum and urine creatinine were calculated and the creatinine clearance was calculated using the following formula: Urine creatinine * Urine volume / Serum creatinine

Intervention groups

1

Description
Intervention group: the first group received 15 mg/kg Amikacin once daily. Intravenous administration of amikacin made by Caspian Iran Company was performed for 7 days.
Category
Treatment - Drugs

2

Description
Intervention group: group received 10 mg/kg of Amikacin twice daily. Intravenous administration of amikacin made by Caspian Iran Company was performed for 7 days.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital
Full name of responsible person
Mojtaba Fazel
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Mojtaba Fazel
Position
Assistant Professor
Latest degree
Subspecialist
Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

No - There is not 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

Yes - There is 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

Title and more details about the data/document

The data obtained from the study process recorded in the questionnaires and SPSS software will be provided to the journal if necessary for the submission of the article or at the request of the journal reviewer.

When the data will become available and for how long

From the time of article submission until any time after which data needs to be provided.

To whom data/document is available

If the journal is required to provide data in a supplementary file, all persons can access the data, and if the journal has requested the data, the reviewers and the journal editorial team can access it.

Under which criteria data/document could be used

The data can be used to review the journal's referees upon request, and if requested as a supplemental file by the journal, all researchers can use the data to study or use in their future studies.

From where data/document is obtainable

Dr. Mojtaba Fazel and Dr. Seyed Alireza Adel Barkhordar Imam Khomeini Hospital, Tehran - Children and NICU Ward E-mail: mojtabafazel@yahoo.com

What processes are involved for a request to access data/document

The requesting person gives an email to the given address explaining the reason for requesting access to the data and how to use the data. A letter of commitment form stating that the data will not be misused and violated copyright law will be signed by the applicant. After reviewing the request and consulting with the project partners, if the request is approved, data will be provided within 2-3 weeks.

Comments