Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Nov 2026

Clinical trial of comparison between use of intravenous aminoglycosides versus intravenous and nebulize aminoglycosides in cystic fibrosis patients

Protocol summary

Study aim
Comparison between use of intravenous aminoglycosides versus intravenous and nebulize aminoglycosides in cystic fibrosis patients

Design
Randomized, parallel-group trial with blinded intervention and outcome assessment. Randomization was centralized and computerized with a concealed randomization sequence carried out at https://www.sealedenvelope.com/.

Settings and conduct
In this study, 80 children with Cystic fibrosis and have referred with acute pulmonary exacerbation in Mofid children hospital will enroll in the study after getting informed consent from parents. The patients will be divided into two groups, and a drug package with a unique code will be delivered to them. The patient, the caregiver, and the investigator will be blind to the package content

Participants/Inclusion and exclusion criteria
Inclusion criteria: Cystic fibrosis patients between ages of 6 to 18 years old with acute pulmonary exacerbations, and are candidates for receiving Aminoglycoside antibiotics. Exclusion criteria : chronic kidney disease, hepatic failure, metabolic disorder, myopathy, hearing loss, neuromuscular disease, electrolyte disturbances

Intervention groups
In one group, patients receive Ceftazidime 50 milligrams per kg three times a day as intravenous, Amikacin 20 milligrams per kg one time a day as intravenous and Normal saline as nebulize one time a day and in the other group receive Ceftazidime 50 milligrams per kg three times a day as intravenous, Amikacin 20 milligrams per kg one time a day as intravenous and Amikacin 500 milligrams as nebulize one time a day.

Main outcome variables
Forced expiratory volume in the first second (FEV1)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120415009475N10**
Registration date: **2021-06-19, 1400/03/29**
Registration timing: **registered_while_recruiting**

Last update: **2021-06-19, 1400/03/29**
Update count: **0**

Registration date
2021-06-19, 1400/03/29

Registrant information

Name
Bahador Mirrahimi

Name of organization / entity
Shahid Beheshti University of Medical Sciences, Faculty of Pharmacy

Country
Iran (Islamic Republic of)

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+98 21 8820 0118

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-05-05, 1400/02/15

Expected recruitment end date
2022-05-05, 1401/02/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Clinical trial of comparison between use of intravenous aminoglycosides versus intravenous and nebulize aminoglycosides in cystic fibrosis patients

Public title
comparison between intravenous aminoglycosides versus nebulize aminoglycosides in cystic fibrosis patients

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
cystic fibrosis flare up
Exclusion criteria:
chronic kidney disease hepatic failure metabolic disorder myopathy hearing loss neuromuscular disease electrolyte disturbances

Age
From **6 years** old to **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
The randomization has been performed using the permuted block randomization table. The block randomization method is designed to randomize subjects into groups that result in equal sample sizes. This method is used to ensure a balance in sample size across groups over time. In our study, subjects will be randomized in 4 patient blocks. Randomization was centralized and computerized with a concealed randomization sequence carried out at https://www.sealedenvelope.com/.

Blinding (investigator's opinion)
Triple blinded

Blinding description
The drug and placebo will be in coded same packages; a designated person will provide the codes from permuted block randomization via phone. The same person will group the data at the end of the trial, and the expert will perform statistical analysis and after results, the pocket that is with the placebo provider would be opened, and the data will be decrypted. The data regarding harm and benefits of treatment will be provided to the patient and caregiver.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
institutional ethics committee for Pharmacy, Nursing and Midwifery Schools

Street address
2nd floor, School of Nursing and Midwifery, Valiasr and Niayesh junction

City
Tehran

Province
Tehran

Postal code
1546815514

Approval date
2021-05-18, 1400/02/28

Ethics committee reference number
IR.SBMU.PHARMACY.REC.1400.039

Health conditions studied

1

Description of health condition studied
cystic fibrosis

ICD-10 code
E84

ICD-10 code description
Cystic fibrosis

Primary outcomes

1

Description
Forced expiratory volume in the first second (FEV1)

Timepoint
in baseline and 14 days after beginning of treatment

Method of measurement
Spirometer

Secondary outcomes

1

Description
Amikacin blood concentration

Timepoint
Before the 4th dose

Method of measurement
Amikacin ELISA Kit

2

Description
Hearing loss
Timepoint
In baseline and 14 days after beginning of treatment
Method of measurement
Auditory Brainstem Response (ABR) testing

3

Description
Serum cratinine
Timepoint
Every 48 hours
Method of measurement
Jaffe's Kinetic Method

4

Description
Hospital stay
Timepoint
Day
Method of measurement
Counting

Intervention groups

1

Description
Intervention group: Ceftazidime 50 milligrams per kg three times a day as intravenous, Amikacin 20 milligrams per kg one time a day as intravenous and Amikacin 500 milligrams as nebulize one time a day
Category
Treatment - Drugs

2

Description
Control group: Ceftazidime 50 milligrams per kg three times a day as intravenous, Amikacin 20 milligrams per kg one time a day as intravenous and Normal saline as nebulize one time a day
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Mofid children's Hospital
Full name of responsible person
Bahador Mirrahimi
Street address
Mirdamad Junction, Shariaty Ave.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr. Seyed Ali Ziaee
Street address
3rd Floor, Faculty of medicine, Arabi Ave, Daneshjoo Blvd, Velenjak.
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1985717443
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mpd@sbmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Amin Rakhshan
Position
Pharmacotherapy Resident
Latest degree
Specialist
Other areas of specialty/work
Clinical pharmacy

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
The main outcome will be available.
When the data will become available and for how long
Six months after publishing
To whom data/document is available
The data will be available per request for people working in academic institutions.
Under which criteria data/document could be used
The data will available for using in systematic review and meta-analysis
From where data/document is obtainable
The data will be available by contacting email; mirrahimi@sbmu.ac.ir
What processes are involved for a request to access data/document
The data will available for using in systematic review and meta-analysis
Comments