

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 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)

##### Phone

+98 21 8820 0118

##### Email address

mirrahimi@sbmu.ac.ir

##### 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.

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

1546815514

##### **Phone**

+98 21 2222 7029

##### **Email**

mirrahimi@yahoo.com

## **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.

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

1985717443

##### **Phone**

+98 21 2243 2040

##### **Email**

mpd@sbm.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

**Street address**

School of Pharmacy, Shahid Beheshti University of  
Medical Sciences, Niayesh junction, Valiasr Ave,  
Tehran, Iran

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**Province**

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1985717443

**Phone**

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**Email**

aminrakhshan@gmail.com

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

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Dr. Bahador Mirrahimi

**Position**

Asistant Profesor, Pharmacotherapy

**Latest degree**

Specialist

**Other areas of specialty/work**

Clinical pharmacy

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Ave.

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

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Dr. Bahador Mirrahimi

**Position**

Asistant Profesor, Pharmacotherapy

**Latest degree**

Specialist

**Other areas of specialty/work**

Clinical pharmacy

**Street address**

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Ave

**City**

Tehran

**Province**

Tehran

**Postal code**

1546815514

**Phone**

+98 21 2222 7020

**Email**

mirrahimi@sbmu.ac.ir

**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**