

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Comparison of Ceftazidime and Ciprofloxacin as antimicrobial prophylaxis in pediatric undergoing Hematopoietic stem cell transplant patients

#### Protocol summary

##### Study aim

Determination of efficacy and safety of ciprofloxacin in the prevention of neutropenic fever in children

##### 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 undergoing hematopoietic stem cell transplantation hospitalized 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: pediatric patients aged from one month to eighteen years undergoing hematopoietic stem cell transplantation. Exclusion criteria: sensitivity to Ciprofloxacin or ceftazidime, Cardiac disease.

##### Intervention groups

In one group, patients receive Ciprofloxacin ten milligrams three times a day and in the other group receive Ceftazidime fifty milligrams three times a day as an injectable drug.

##### Main outcome variables

Days without neutropenic fever

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20120415009475N8**

Registration date: **2020-08-04, 1399/05/14**

Registration timing: **prospective**

Last update: **2020-08-04, 1399/05/14**

Update count: **0**

##### Registration date

2020-08-04, 1399/05/14

##### 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

2020-08-22, 1399/06/01

##### Expected recruitment end date

2021-08-23, 1400/06/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of Ceftazidime and Ciprofloxacin as antimicrobial prophylaxis in pediatric undergoing Hematopoietic stem cell transplant patients

##### Public title

Ceftazidime and Ciprofloxacin in the prevention of infection in children under transplantation

##### Purpose

Prevention

**Inclusion/Exclusion criteria**

**Inclusion criteria:**  
pediatric patients undergo stem cell transplantation

**Exclusion criteria:**  
Penicillin allergy Quinolone allergy Congenital Arrhythmia

**Age**  
From **1 month** old to **18 years** old

**Gender**  
Both

**Phase**  
3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- 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**  
Not 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 Ave and Niayesh Highway junction

### **City**

Tehran

### **Province**

Tehran

### **Postal code**

1546815514

### **Approval date**

2020-03-02, 1398/12/12

### **Ethics committee reference number**

IR.SBMU.PHARMACY.REC.1398.333.

## Health conditions studied

### 1

#### **Description of health condition studied**

Neutropenic fever in pediatric Hematopoietic stem cell transplantation

#### **ICD-10 code**

T86.0

#### **ICD-10 code description**

Complications of bone marrow transplant

## Primary outcomes

### 1

#### **Description**

Days without neutropenic fever from start of transplantation

#### **Timepoint**

Days

#### **Method of measurement**

Temperature measurement and White blood cell count

## Secondary outcomes

### 1

#### **Description**

Hospital stay

#### **Timepoint**

Days

#### **Method of measurement**

Counting

### 2

#### **Description**

White blood cell recovery time

#### **Timepoint**

Days

#### **Method of measurement**

The days until patient having two consecutive White blood cell counts above 1000 cells in milli Litre.

## Intervention groups

### 1

#### Description

Intervention group: Ciprofloxacin ten milligrams three times a day as an injectable drug

#### Category

Prevention

### 2

#### Description

Intervention group: receive ceftazidime fifty milligrams three times a day as an injectable drug

#### Category

Prevention

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Mofid children's Hospital

##### Full name of responsible person

Bahador Mirrahimi

##### Street address

Mofid Children's Hospital, 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

1985717434

##### Phone

+98 21 2243 9951

##### 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

Dr. Bahador Mirrahimi

##### Position

Asistant Profesor, Pharmacotherapy.

##### Latest degree

Specialist

##### Other areas of specialty/work

##### Street address

Mofid children's Hospital, Miradmad Junction, Shariaty Ave.

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##### Phone

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##### Email

mirrahimi@sbm.ac.ir

##### Web page address

## 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

Medical Pharmacy

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**Fax****Email**

mirrahimi@sbmu.ac.ir

**Web page address****Fax****Email**

mirrahimi@sbmu.ac.ir

**Web page address****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 data.

**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 use 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 request with the systematic review protocol will be reviewed and answered in two weeks.

**Comments****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

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