

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

Comparison of The Efficacy of Levofloxacin and Ciprofloxacin in Prevention of Bacterial Infection in Allogeneic Hematopoietic Stem Cell Transplant Recipients

Protocol summary

Study aim

Comparison of The Efficacy of Levofloxacin and Ciprofloxacin in Prevention of Bacterial Infection in Allogeneic Hematopoietic Stem Cell Transplant Recipients

Design

Two arm parallel group randomized trial with non blinded outcome assessment

Settings and conduct

in this randomized controlled trial, patients who admitted to bone marrow transplant ward from Taleqani hospital affiliated to Shahid Beheshti University of Medical Sciences who are candidate to receive allogenic hematopoietic stem cell transplant will enrolled. patients will be randomized in two groups of thirty (one group will receive Ciprofloxacin and another receive Levofloxacin). in each group patients will receive their antibiotic till engraftment or fever detection .

Participants/Inclusion and exclusion criteria

Inclusion criteria: Candidate for Allogeneic Stem Cell Transplantation; age over 18 Non-inclusion criteria: Chronic Kidney Disease; Age over 65; pregnancy; Unwillingness to participate in the study; Fever before engraftment ; Fever before 21 days after transplantation; Patients death

Intervention groups

Intervention group 1: Patients receiving Levofloxacin
Intervention group 2: Patients receiving Ciprofloxacin

Main outcome variables

Confirmed infection Fever detection; Engraftment time;
Time of fever detection

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100127003210N17**

Registration date: **2019-08-23, 1398/06/01**

Registration timing: **registered_while_recruiting**

Last update: **2019-08-23, 1398/06/01**

Update count: **0**

Registration date

2019-08-23, 1398/06/01

Registrant information

Name

Maria Tavakoli Ardakani

Name of organization / entity

Faculty of pharmacy, Shaid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8887 3704

Email address

mariatavakoli@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-20, 1397/12/01

Expected recruitment end date

2019-10-23, 1398/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of The Efficacy of Levofloxacin and

Ciprofloxacin in Prevention of Bacterial Infection in Allogeneic Hematopoietic Stem Cell Transplant Recipients

Public title
Levofloxacin in Hematopoietic stem cell transplant

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Candidate for Allogeneic Stem Cell Transplantation Age over 18
Exclusion criteria:
Chronic renal failure Age over 65 Pregnancy Unwillingness to participate in the study

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
The random allocation sequence will computer generate and consist of series of group number (either 1 = A or 2 = B) for each consecutive patient. Block randomization method will use and each block will be consist of 10 patients. Each block includes 5 patients who will receive Vitamin E and 5 patients from control group

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

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

Niayesh Highway, Valiasr Ave, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

6153- 14155

Approval date

2019-01-28, 1397/11/08

Ethics committee reference number

IR.SBMU.Pharmacy.REC.1397.217

Health conditions studied

1

Description of health condition studied

antibiotic prophylaxis in hematopoietic stem cell transplantation

ICD-10 code

T86.0

ICD-10 code description

Complications of bone marrow transplant

Primary outcomes

1

Description

fever detection

Timepoint

every 6 hours till engraftment

Method of measurement

Via mercury thermometer

2

Description

Infection

Timepoint

Daily till engraftment happen

Method of measurement

1. Clinical sign and symptoms. 2.Laboratory data

Secondary outcomes

1

Description

Duration of neutropenic status

Timepoint

Daily

Method of measurement

Blood Neutrophile count

2

Description

Hospital length of stay

Timepoint

Daily

Method of measurement

recording number of hospitalized days

3

Description

Need for other antibiotic consumption

Timepoint

Daily

Method of measurement

Patient's medication list

4**Description**

Engraftment time

Timepoint

Daily

Method of measurement

Blood cells count

Intervention groups**1****Description**

Intervention group: receiving Levofloxacin by dose of 500 mg per day in form of one tablet which is taken orally or intravenously if the patient is unable to take orally from day 1 post transplantation for 21 days or detecting fever or engraftment.

Category

Treatment - Drugs

2**Description**

Intervention group: receiving Ciprofloxacin by dose of 500 mg every 12 hours in form of one tablet which is taken orally or intravenously if the patient is unable to take orally from day 1 post transplantation for 21 days or detecting fever or engraftment.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Ayatollah Taleghani hospital

Full name of responsible person

Maria Tavakoli-Ardakani

Street address

Taleghani Educational Hospital, Tabnak St. Velenjak Region, Chamran High Way, Tehran, Iran

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1985711151

Phone

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mariatavakoli@sbmu.ac.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Nima Naderi

Street address

Faculty of Pharmacy-Niyayesh intersection-Valiasr St

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Tehran

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1991953381

Phone

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Email

Mariatavakoli@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

Dr.Omid Moradi

Position

Clinical Pharmacy Resident

Latest degree

Medical doctor

Other areas of specialty/work

Medical Pharmacy

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Niayesh Highway, Valiasr Ave, Tehran, Iran

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Email

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Maria Tavakoli-Ardakani

Position

Associated Professor

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

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Person responsible for updating data

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Name of organization / entity

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Full name of responsible person

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Position

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Latest degree

Specialist

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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

No - There is not a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

Primary outcome data after making unrecognizable will be released

When the data will become available and for how long

6 months after publishing the results primary outcome data will be released

To whom data/document is available

Researchers after allowance of corresponding author could have the permission to have the data

Under which criteria data/document could be used

Performing any analysis will be allowed only with the permission of corresponding author

From where data/document is obtainable

Corresponding author

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

After requesting to reach data, corresponding author will check the allowance, then the researcher will be informed about it

Comments