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 hematopoetic 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-iclusion 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 Ciprofloxcacin

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)

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+98 21 8887 3704

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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 Hematopoetic 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 hematopoetic 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 consuption

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
City
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1985711151
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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. Nima Naderi
Street address
Faculty of Pharmacy-Niyayesh intersection-Valiasr St
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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
Street address
Niayesh Highway, Valiasr Ave, Tehran, Iran
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O_moradi@outlook.com

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

Contact

Name of organization / entity

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Full name of responsible person

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Position

Associated professor

Latest degree

Specialist

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

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