Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Study and comparison of the pharmacokinetics of continuous infusion of linezolid versus intermittent dosing in patients with renal failure

Protocol summary

Study aim
Can a 24-hour linezolid regimen replace the current 12-hour regimen as the standard of care?

Design
A controlled, parallel-group, non-blinded, randomized, phase 3 clinical trial on 40 patients. Excel software was used for randomization.

Settings and conduct
This study will be conducted in the intensive care unit of Sina Hospital in Tehran, with linezolid administered in two forms: continuous infusion and every 12 hours in patients with reduced kidney function. Blood samples will be taken from the patients within 48 hours of the study to check drug levels.

Participants/Inclusion and exclusion criteria
Age over 18 years; suspected or proven Gram-positive infection for which your doctor has prescribed intravenous linezolid; renal filtration rate less than 40 mL/min Hemoperfusion and plasmapheresis and dialysis; Hypersensitivity to linezolid or any of the product's excipients; Pregnancy and lactation

Intervention groups
Linezolid is administered in two forms: 24-hour infusion and every 12 hours in two different groups.

Main outcome variables
Percentage ratio when the plasma concentration of the drug is higher than the MIC in patients; review and comparison of AUC/MIC in the studied patients

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20251202068186N1**
Registration date: **2026-02-17, 1404/11/28**
Registration timing: **prospective**
Last update: **2026-02-17, 1404/11/28**
Update count: **0**

Registration date
2026-02-17, 1404/11/28

Registrant information

Name
Mohammadhasan Mirasheh

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 4486 6264

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mohammadmirasheh30@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2026-03-06, 1404/12/15

Expected recruitment end date
2026-10-28, 1405/08/06

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Study and comparison of the pharmacokinetics of continuous infusion of linezolid versus intermittent dosing in patients with renal failure

Public title
Review of 24-hour linezolid administration

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Over 18 years old Fever greater than 37.8°C Informed consent Leukocytosis above 10,000 cells per cubic millimeter Serum lactate above 18 milligram per decilitre Suspected or proven gram-positive infection for which the treating physician has prescribed intravenous linezolid Glomerular filtration rate less than 40 milliliter per minute

Exclusion criteria:

Pregnancy and breastfeeding Patients undergoing hemoperfusion and plasmapheresis Dialysis Hypersensitivity to linezolid or any of the product's excipients • Taking any compound that inhibits the enzyme mono-amine oxidase A or B Hematological diseases disseminated intravascular coagulation

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants in the study will be randomly assigned to two groups receiving continuous infusion and intermittent administration in a 1:1 ratio using a random number generator in Excel. We use a simple randomization method and the units of randomization are participants. Randomization is performed in an unblinded manner.

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 The Institute of Pharmaceutical Sciences -Tehran University of Medical Sciences

Street address

Second Floor, The Institute Of Pharmaceutical Sciences, Tehran University Of Medical Sciences, 16 Azar Street, Enghelab Square

City

Tehran

Province

Tehran

Postal code

1417614411

Approval date

2026-02-14, 1404/11/25

Ethics committee reference number

IR.TUMS.TIPS.REC.1404.162

Health conditions studied

1

Description of health condition studied

the pharmacokinetics of continuous infusion of linezolid versus intermittent dosing in patients with renal failure

ICD-10 code

N18.3

ICD-10 code description

Chronic kidney disease, stage 3 (moderate)

Primary outcomes

1

Description

Percentage of time when the plasma concentration of the drug is above the Minimum Inhibitory Concentration patients

Timepoint

Samples were measured at times before starting the drug (time zero), 1.5, 2, 4, 8, 12, 5.13, 24, 5.25, 36 and 48 hours after starting linezolid.

Method of measurement

High Performance Liquid Chromatography Device

2

Description

area under the concentration-time curve

Timepoint

End of sampling

Method of measurement

Concentration-time curve

Secondary outcomes

1

Description

Blood platelet levelدر

Timepoint

At the beginning of the study and at the end of the study

Method of measurement

Number per microliter of blood

2

Description

Albumin to lactate ratio

Timepoint

The beginning and end of the study

Method of measurement

Blood albumin and lactate levels

Intervention groups

1

Description
Intervention group: Receiving the Linezolid from Shahid Ghazi Company as a 24-hour continuous infusion at a rate of 50 mg per hour and a loading dose of 600 mg over one hour
Category
Treatment - Drugs

2

Description
Control group: Receiving Linezolid from Shahid Ghazi Company in the form of 600 mg every 12 hours, which is infused for one hour
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Sinai lospital
Full name of responsible person
Mojtaba Mojtahedzadeh
Street address
Sina hospital., before Hassan Abad Square., Imam Khomeini St., Tehran
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Web page address

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Ramin Kordi
Street address
Vice President for Research and Technology., 6th Floor., Central University Organization., corner of Qods Street., Keshavarz Boulevard
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141765383761
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vcr@tums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Rational Drug Prescription Research Center
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
Tehran University of Medical Sciences
Full name of responsible person
Mojtaba Mojtahedzadeh
Position
Professor
Latest degree
Subspecialist
Other areas of specialty/work
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Person responsible for scientific inquiries

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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
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not 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
Not applicable
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
Data on patient characteristics such as age, gender, and medications, as well as information on the main and secondary outcomes of the intervention after de-identifying the individuals.
When the data will become available and for how long
The start of the access period after the end of the study and printing of the results
To whom data/document is available
Allowing access to researchers of academic and hospital institutions
Under which criteria data/document could be used
Statistical analyses
From where data/document is obtainable
1-Dr. Mojtabi Mojtahedzadeh mojtahed@sina.tums.ac.ir 2-Dr. Mohammadreza Rouini rouini@tums.ac.ir 3-Dr. Seyed Hamidreza Sharif Nia tumspr@tums.ac.ir 4-Dr. Mohammad Hassan Mirasheh mohammadmirasheh30@gmail.com
What processes are involved for a request to access data/document
First, the applicant must send the documents that he requests access to by e-mail, stating the reason and details, to the researchers of this project (given in the previous box), and then after reviewing and consulting, these documents will be sent to him.
Comments