Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Investigation and comparison of the effect of changing the drug regimen containing carbapenem to piperacillin/tazobactam in the treatment of hospitalized cancer patients with fever and neutropenia

Protocol summary

Study aim

Investigation and comparison of changing drug regimen containing carbapenem to piperacillin/tazobactam in treatment Cancer patients with fever and neutropenia

Design

Clinical trial with two study arms, with parallel groups, randomized without blinding

Settings and conduct

In this randomized clinical trial, cancer patients admitted to the oncology department of Taleghani Hospital affiliated to Shahid Beheshti University of Medical Sciences who have fever and neutropenia will be included in the study. In this study, 60 patients with fever and neutropenia will be randomly selected. They will be studied in two groups of 30 people (one group receiving carbapenem and one group receiving piperacillin/tazobactam). The patients of each group will receive the medicine from day +1 until the day when the symptoms of fever and neutropenia disappear.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Cancer patients with fever (above 38.3 degree) and neutropenia(absolute netrophil count below 500 per microliter) Age above 18 years exclusion criteria: Pregnancy Unwillingness to participate in the study Patients with central vein catheter Prophylactic antibiotic use before starting the study

Intervention groups

Intervention group 1: Patients receiving carbapenem
Intervention group 2: Patients receiving piperacillin/tazobactam

Main outcome variables

Confirmed infection Fever detection; Neutrophil count less than 500 per milliliter; Fever above 38.3 degrees Celsius

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100127003210N27**
Registration date: **2023-06-27, 1402/04/06**
Registration timing: **prospective**

Last update: **2023-06-27, 1402/04/06**
Update count: **0**

Registration date

2023-06-27, 1402/04/06

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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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-06, 1402/04/15

Expected recruitment end date

2024-07-05, 1403/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Investigation and comparison of the effect of changing the drug regimen containing carbapenem to piperacillin/tazobactam in the treatment of hospitalized cancer patients with fever and neutropenia

Public title
Comparison the effectiveness of carbapenems and piperacillin/tazobactam in treatment of hospitalized cancer patients with fever and neutropenia

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Age over 18 Cancer patients with fever (above 38.3 degree) and neutropenia(absolute neutrophil count below 500 per microliter) Hospitalized patients
Exclusion criteria:
Pregnancy Unwillingness to participate in the study Patients with central vein catheter Prophylactic antibiotic use before starting the study

Age
From **18 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
In this study, with the help of permuted block randomization method and using online statistical randomization software, the patients of each group are divided into 2 blocks of 15 people based on the type of disease (malignancy) and age. The allocation and distribution of blocks is done with the help of software, and a code created with the help of the software is assigned to each sample.

Blinding (investigator's opinion)
Single 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 Behesti University of Medical Sciences
Street address
Faculty of Pharmacy, Shahid Beheshti University of Medical Science, Valiasr St., Hashemi Rafsanjani Highway intersection., Tehran, Iran.
City
Tehran
Province
Tehran
Postal code
1996835113

Approval date
2022-08-10, 1401/05/19

Ethics committee reference number
IR.SBMU.Pharmacy.REC.1401.094

Health conditions studied

1

Description of health condition studied
Fever and neutropenia in cancer patients

ICD-10 code
D70

ICD-10 code description
Neutropenia

Primary outcomes

1

Description
Fever above 38.3 degrees Celsius

Timepoint
Every 6 hours a day

Method of measurement
Via mercury thermometer

2

Description
Neutrophil count less than 500 per milliliter

Timepoint
Every 24 hours

Method of measurement
1.Clinical signs and symptoms; 2.Laboratory data

Secondary outcomes

1

Description
Hospital length of stay

Timepoint
Daily

Method of measurement
Recording number of hospitalized days

2

Description
Duration of neutropenic status
Timepoint
Daily
Method of measurement
Blood Neutrophil count

3

Description
Need for other antibiotic consuption
Timepoint
Daily
Method of measurement
Patient's medication list

Intervention groups

1

Description
The first intervention group: receiving imipenem at a dose of 500 mg every 6 hours or meropenem 1000 mg every 8 hours in the form of an injection vial until the patient's fever resolves and the patient's neutrophil count increases to more than 500 per ml. .
Category
Treatment - Drugs

2

Description
Intervention group: receiving piperacillin/tazobactam at a dose of 4.5 grams every 8 hours (according to the dose of piperacillin) in the form of an injection vial and evaluating the patients after 72 and 96 hours after the start of antibiotic use.
Category
Treatment - Drugs

3

Description
Intervention group: If there is no improvement and no reduction in fever in patients after 72 hours of starting piperacillin/tazobactam and observing evidence of gram-positive bacteria, we prescribe vancomycin at a dose of 1 gram every 12 hours.
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
Tehran, Shahid Chamran Highway, Yemen St., Shahid Arabi St.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Afshin Zarghi
Street address
Tehran, Shahid Chamran Highway, Yemen St., Shahid Arabi St., Building No. 2, Fifth Floor
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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

Maria Tavakoli Ardakani
Position
Professor
Latest degree
Specialist
Other areas of specialty/work
Medical Pharmacy
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Person responsible for updating data

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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
Therapeutic findings of the intervention can be shared by statistical analysis without providing patient names.
When the data will become available and for how long
6 month after publishing the results, primary outcome data will be released.
To whom data/document is available
Doctors and other researchers in the field of infection and neutropenic fever
Under which criteria data/document could be used
People such as hospital staff or other medical staff such as nurses and clinical pharmacists can use this information.
From where data/document is obtainable
Researchers can contact the following email to receive information: mariatavakoli@yahoo.com
What processes are involved for a request to access data/document
People who intend to use the information must be affiliated with reliable organizations and their requests should be submitted through these organizations. In this context, there is a need for an introduction letter from the desired center.
Comments