

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jun 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 neutrophil 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)

Phone

+98 21 8887 3704

Email address

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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 consumption

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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Email

taleghani@sbmu.ac.ir

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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Tehran, Niayesh - Valiasr intersection, Niayesh educational complex, Shahid Beheshti faculty of pharmacy

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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

Maria Tavakoli Ardakani

Position

Associate 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Zakieh Dehbashi

Position

Pharm D student

Latest degree

A Level or less

Other areas of specialty/work

Medical Pharmacy

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Zakiehdehbashi@yahoo.com

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