

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Comparison of clinical outcomes of treatment with cefepime monotherapy vs aminoglycoside-ceftriaxone combination in children with chemotherapy induced fever and neutropenia

Protocol summary

Study aim

Comparison of mean length of hospital stay between the ceftriaxone and aminoglycoside group with the cefpime group

Design

Clinical trial with control group, parallel, single blind, randomized, phase 3 with 60 episodes of fever and neutropenia. Sealedenvelop.com was used for randomization.

Settings and conduct

Motahhari Children's Hospital in Urmia, children with fever and neutropenia due to chemotherapy, children are divided into two groups: Motahhari and American Society of Clinical Oncology and tests are taken. In patients whose culture is positive during the study, the antibiotic regimen will be readjusted according to the culture result. Also, if there is no clinical improvement after 72 hours, the patient's antibiotics will change to a higher level of microbial coverage, and in case of deterioration after 96 hours, antifungal will be added to the treatment regimen. Data analyzer is blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- Age between 3 months to 18 years
2- Diagnosis of fever and neutropenia (oral temperature ≥ 38.3 at one measurement or ≥ 38 temperature that lasts for one hour, with $500 \text{ ANC} <$)
3- Cancer
4- Consent of the parent or legal guardian to participate in the study protocol
5- No contraindications for receiving the studied antibiotics (gentamicin, amikacin, ceftriaxone, cefpime)
Inclusion criteria: 1- Patients with a history of type 1 allergy to one of the above antibiotics
3- Patients who have a specific microorganism at the beginning of the culture
2- Critical patients who need extensive antibiotic coverage from the beginning of hospitalization

Intervention groups

Motahhari (M) group: gentamicin/amikacin + ceftriaxone
ASCO (A) group: cefepime

Main outcome variables

Mean duration of ICU and hospital stay, frequency of need to escalate antibiotic regimen, mean duration required to stop fever, mean changes in laboratory data

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151205025372N3**

Registration date: **2021-11-10, 1400/08/19**

Registration timing: **registered_while_recruiting**

Last update: **2021-11-10, 1400/08/19**

Update count: **0**

Registration date

2021-11-10, 1400/08/19

Registrant information

Name

Zahra Alimohammad Ghelichkhan

Name of organization / entity

Urmia University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-23, 1400/08/01

Expected recruitment end date

2022-10-23, 1401/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of clinical outcomes of treatment with cefepime monotherapy vs aminoglycoside-ceftriaxone combination in children with chemotherapy induced fever and neutropenia

Public title

Comparison of cefpime with a combination of gentamicin or amikacin and ceftriaxone in chemotherapy-induced fever in children

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age between 3 months to 18 years Diagnosis of fever and neutropenia (oral temperature ≥ 38.3 at one measurement or ≥ 38 temperature that lasts for one hour, with ANC < 500) Cancer Consent of the parent or legal guardian to participate in the study protocol No contraindications for receiving the studied antibiotics (gentamicin, amikacin, ceftriaxone, cefepime)

Exclusion criteria:

Patients with a history of type 1 allergy to one of the above antibiotics Patients who have a positive culture with specific microorganism on admission Patients in need who need extensive antibiotic coverage from the beginning of hospitalization

AgeFrom **3 months** old to **18 years** old**Gender**

Both

Phase

3

Groups that have been masked

- Data analyser

Sample sizeTarget sample size: **60****Randomization (investigator's opinion)**

Randomized

Randomization description

Patients entering the study are assigned to one of two control or intervention groups using block randomization, with block size 4 through a sealed envelope. This envelope is created by sealedenvelope.com by specifying the sample size and block size and using a random seed. Due to the creation of the final random code for each patient, it is unclear to the researcher which patient will be studied in which arm.

Blinding (investigator's opinion)

Single blinded

Blinding description

The person who analyzes the data at the end does not know the allocation of study groups

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Urmia University of Medical Sciences

Street address

Orjhans Alley, Resalat Blvd.

City

Urmia

Province

West Azarbaijan

Postal code

5714783734

Approval date

2021-09-25, 1400/07/03

Ethics committee reference number

IR.UMSU.REC.1400.245

Health conditions studied**1****Description of health condition studied**

fever and neutropenia due to chemotherapy

ICD-10 code

D70.1

ICD-10 code description

Agranulocytosis secondary to cancer chemotherapy

Primary outcomes**1****Description**

Mean hospital stay

Timepoint

After discharge

Method of measurement

Counting days

2**Description**

Mean ICU stay

Timepoint

After discharge

Method of measurement

Counting days

3

Description

Frequency of the need to escalate the antibiotic regimen

Timepoint

After discharge

Method of measurement

Checking the patient's file

4

Description

The mean duration required to stop the fever

Timepoint

After discharge

Method of measurement

Counting days

Secondary outcomes

1

Description

Mean ICU stay

Timepoint

After discharge

Method of measurement

Counting days

2

Description

Frequency of the need to escalate the antibiotic regimen

Timepoint

After discharge

Method of measurement

Checking the patient's file

3

Description

The mean duration required to stop the fever

Timepoint

After discharge

Method of measurement

Counting days

Intervention groups

1

Description

Intervention group: Cefpime 50mg / kg every eight hours

Category

Treatment - Drugs

2

Description

Control group: aminoglycoside (gentamicin 2-2.5 mg / kg every eight hours / amikacin 15-22.5 mg / kg daily in three divided doses) + ceftriaxone 50-100 mg / kg daily in one or two doses

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Motahari children's hospital

Full name of responsible person

Sara Mohsenzadeh

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Kashani street

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Phone

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Fax

Email

Sarahmzd96@gmail.com

Web page address

<https://motahari.umsu.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Dr Iraj Mohebbi

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mohebbi_iraj@yahoo.co.uk

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Oroumia 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
Oroumia University of Medical Sciences
Full name of responsible person
Zahra Alimohammad Ghelichkhan
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Undecided

When the data will become available and for how long

Undecided

To whom data/document is available

Undecided

Under which criteria data/document could be used

Undecided

From where data/document is obtainable

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

Undecided
Comments