Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Jun 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 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, ceftrixone, 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
Age
From **3 months** old to **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Data analyser

Sample size
Target 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 hosptial 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
Street address
Kashani street
City
Urmia
Province
West Azarbaijan
Postal code
57146154637
Phone
+98 44 3222 7002
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
Street address
Deputy of Research and Technology, Urmia University of Medical Sciences, Orjhans Street, Resalat Blvd.
City
Urmia
Province
West Azarbaijan
Postal code
5714783734
Phone
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Email
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

Medical Pharmacy

Street address

Clinical Pharmacy Department, School of Pharmacy, Urmia University of Medical Sciences, Pardis Nazlou, 11 km of Nazlou Road

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Contact

Name of organization / entity

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Full name of responsible person

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Person responsible for updating data

Contact

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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