Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The efficacy of ciprofloxacin in preventing infection among patients with chemotherapy induced neutropenia in a university medical center in Iran

Protocol summary

Summary

Our objective was to assess the efficacy of oral ciprofloxacin in preventing fever and infection among neutropenic patients. In this unicenter double blinded phase 2 randomized controlled clinical trial, we enrolled male and female patients aged 17 to 80 with solid or hematologic neutropenia who were diagnosed neutropenic following chemotherapy without fever and any history of recent antibiotic usage. 120 neutropenic patients after confirming not to have fever or consumption of antibiotics in last 7 days were randomized into two 60 person groups. The first group received oral ciprofloxacin, 500 mg/bid and the second group received similar placebo. The interventions were continued until occurrence of fever or resolution of neutropenic in non-febrile patients. The main outcome was fever occurrence and secondary outcomes were occurrence of bacterial infection and death.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015092924266N1**
Registration date: **2016-02-11, 1394/11/22**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-02-11, 1394/11/22

Registrant information

Name

Reza Ghalehtaki

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6119 2520

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Recruitment status

Recruitment complete

Funding source

AJA University, Committee of Research

Expected recruitment start date

2013-07-01, 1392/04/10

Expected recruitment end date

2015-06-30, 1394/04/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The efficacy of ciprofloxacin in preventing infection among patients with chemotherapy induced neutropenia in a university medical center in Iran

Public title

The efficacy of ciprofloxacin in preventing infection among patients with chemotherapy induced neutropenia in a university medical center in Iran

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Absolute neutrophil count < 500 or less 1000 with predicted fall to below 500 in 48-72 hours; History of Malignancy. Exclusion criteria: Fever or Any sign of clinical or microbiological infection; Any history of antibiotic consumption lately before admission.

Age

From **17 years** old to **80 years** old

Gender

Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of the AJA University of Medical Sciences
Street address
Ethics committee of the AJA University of Medical Sciences, Etemadian Avenue, Fatemi Street, Tehran, Iran
City
Tehran
Postal code
Approval date
2013-07-10, 1392/04/19
Ethics committee reference number
9206

Health conditions studied

1

Description of health condition studied
Neutropenia
ICD-10 code
D70
ICD-10 code description
Agranulocytosis

2

Description of health condition studied
Fever
ICD-10 code
R50.9
ICD-10 code description
Fever, unspecified

Primary outcomes

1

Description
Fever
Timepoint
After intervention
Method of measurement
Body core temperature by Thermometer

Secondary outcomes

1

Description
Bacterial Infection
Timepoint
After intervention
Method of measurement
Blood, urine or sputum culture

Intervention groups

1

Description
Intervention: Administration of Oral tablets of Ciprofloxacin 500 mg/bid after diagnosis of neutropenia until occurrence of fever or resolution of neutropenia
Category
Prevention

2

Description
Control: Administration of Oral tablets of Placebo /bid after diagnosis of neutropenia until occurrence of fever or resolution of neutropenia
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza (501) Hospital of IRI army
Full name of responsible person
Ali Asgari
Street address
Imam Reza (501) Hospital of IRI army, Etemadian Avenue, Fatemi Street, Tehran, Iran
City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
AJA University of Medical Sciences

Full name of responsible person
Dr Banafsheh Dormansesh, Deputy of Research, AJA University of Medical Sciences

Street address
AJA University of Medical Sciences, Etemadian ave., Fatemi Street

City
Tehran

Grant name

Grant code / Reference number

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

Title of funding source
AJA University of Medical Sciences

Proportion provided by this source
100

Public or private sector
empty

Domestic or foreign origin
empty

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
Infectious Diseases Research Center, AJA University of Medical Sciences

Full name of responsible person
Ali Asgari

Position
Faculty/Assistant professor/MD

Other areas of specialty/work

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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty