

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jun 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

Email address

r-ghaletaki@student.tums.ac.ir

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**Street address**

AJA University of Medical Sciences, Etemadian Avenue, Fatemi Street, Tehran, Iran

City

Tehran

Postal code**Phone**

+98 21 8454 9913

Fax**Email**

aliasgari222@gmail.com

Web page address

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Infectious Diseases Research Center, AJA university of medical sciences

Full name of responsible person

Ali Asgari

Position

Faculty/ MD

Other areas of specialty/work**Street address**

AJA University of Medical Sciences, Etemadian Avenue, Fatemi Street, Tehran, Iran

City

Tehran

Postal code**Phone**

+98 21 8454 9913

Fax**Email**

aliasgari222@gmail.com

Web page address

Person responsible for updating data

Contact**Name of organization / entity**

AJA University of Medical Sciences

Full name of responsible person

Ali Asgari

Position

Faculty/ Assistant Professor

Other areas of specialty/work**Street address**

AJA University of Medical Sciences, Etemadian Avenue, Fatemi Street, Tehran, Iran

City

Tehran

Postal code**Phone**

+98 21 8454 9913

Fax**Email**

aliasgari222@gmail.com

Web page address

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