

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

Comparison of efficacy in therapy with cefixime plus azithromycin versus high-dose amoxicillin plus azithromycin among patients with pneumonia

Protocol summary

Summary

The aim of this randomized single blind controlled trial is to investigate the efficacy of two drug regimens in the treatment of pneumonia. In this trial, 82 patients aged over 12 years old with pneumonia referred to Infectious clinic of Beheshti Hospital, are randomly assigned to the intervention or control groups. The patients in the first group will receive high-dose amoxicillin (1 mg TDS) plus azithromycin 500 mg stat and 250 mg daily and in the second group will receive cefixime 400 mg daily plus azithromycin 500 mg stat and 250 mg daily. Primary outcomes are response to the treatment based on the fever, cough, and clinical symptoms.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201107096922N2**

Registration date: **2011-08-08, 1390/05/17**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-08-08, 1390/05/17

Registrant information

Name

Afsaneh Karami

Name of organization / entity

Zanjan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 24 1727 0801

Email address

rastin@zums.ac.ir

Recruitment status

Recruitment complete

Funding source

Zanjan University of Medical Sciences

Expected recruitment start date

2008-02-20, 1386/12/01

Expected recruitment end date

2008-09-01, 1387/06/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of efficacy in therapy with cefixime plus azithromycin versus high-dose amoxicillin plus azithromycin among patients with pneumonia

Public title

Efficacy of two drug regimens in the treatment of pneumonia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: out-patients with pneumonia, age over 12 years Exclusion criteria: inpatients with pneumonia; Failure to refer the patient

Age

From **12 years** old to **82 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **82**

Randomization (investigator's opinion)

N/A

Randomization description

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
Zanjan University of Medical Sciences

Street address
Zanjan University of Medical Sciences, Azadi St.,
Zanjan

City
Zanjan

Postal code

Approval date
2010-09-23, 1389/07/01

Ethics committee reference number
1390415

Health conditions studied

1

Description of health condition studied

Efficacy of cefixime in pneumonia treatment

ICD-10 code
J15, J15.9

ICD-10 code description
Bacterial pneumonia, not elsewhere classified & Bacterial pneumonia, unspecified

Primary outcomes

1

Description
patient's general appearance

Timepoint
after 1 week and after the treatment (10th day)

Method of measurement
physical exam

2

Description
fever

Timepoint
after 1 week and after the treatment (10th day)

Method of measurement
termometer

3

Description
cough

Timepoint
after 1 week and after the treatment (10th day)

Method of measurement
patient's complaint and daily notes

4

Description
lung auscultation to normal

Timepoint
after 1 week and after the treatment (10th day)

Method of measurement
lung auscultation with stethoscope

Secondary outcomes

1

Description
shock

Timepoint
after 1 week and after the treatment (10th day)

Method of measurement
measurement of BP

2

Description
respiratory failure

Timepoint
after 1 week and after the treatment (10th day)

Method of measurement
physical exam

3

Description
level of consciousness

Timepoint
after 1 week and after the treatment (10th day)

Method of measurement
physical exam

Intervention groups

1

Description
Cefixime 400mg / day orally for 10 days + Azithromycine
500 mg stat and 250mg daily orally

Category
Treatment - Drugs

2

Description

Amoxicillin 1gr TDS for 10 days orally + Azithromycine
500 mg stat and 250mg daily orally

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Infectious ward- Shahid Beheshti Hospital- Zanjan-
Iran

Full name of responsible person

Afsaneh Karami MD

Street address

Infectious ward- Vali-Asr Hospital - Zanjan

City

Zanjan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Registry center

Street address

Zanjan University of Medical Sciences, Azadi St.,
Zanjan

City

Zanjan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Zanjan 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

Zanjan University of Medical Sciences

Full name of responsible person

Afsaneh Karami

Position

Infectious Specialist

Other areas of specialty/work

Street address

Vali-Asr Hospital - Zanjan- Iran

City

zanjan

Postal code

Phone

+98 24 1727 0801

Fax

Email

Rastin@zums.ac.ir Dr.akarami@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Afsaneh Karami

Position

Infectious specialist

Other areas of specialty/work

Street address

Infectious ward- valiasr Hospital - Zanjan- Iran

City

Zanjan

Postal code

Phone

+98 24 1727 0801

Fax

Email

Rastin@zums.ac.ir dr.akarami@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Afsaneh Karami

Position

Infectious and Tropical disease specialist

Other areas of specialty/work

Street address

Infectious ward- Valiasr Hospital -Zanjan- Iran

City

Zanjan

Postal code

Phone

+98 24 1727 0801

Fax

Email

Rastin@zums.ac.ir dr.akarami@yahoo.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