Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 stetoscope

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 consiousness

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
Registery 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