

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Sep 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*