

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jul 2026

### Comparison between cefixime and co-amoxiclavate therapeutic effects in outpatient treatment of acute community acquired pneumonia

#### Protocol summary

##### Summary

the purpose of this triple blind clinical trial is to compare between cefixime and co-amoxiclavate therapeutic effects in outpatient treatment of acute community acquired pneumonia. in this study 310 CAP patients treated in Arak University clinics are going to divide into 2 groups(co-amoxiclavate 625mg/tds and cefixime 400mg/day for 2 weeks) randomly. therapeutic effects of the drugs will be evaluate in 2th and 4th week after treatment and will be compare to first visit evaluation between both groups.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201111186056N4**  
Registration date: **2011-11-21, 1390/08/30**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2011-11-21, 1390/08/30

##### Registrant information

##### Name

Nader Zarinfar

##### Name of organization / entity

Arak University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 86 1224 1411

##### Email address

zarinfar@arakmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice Chancellor for Research of Arak University of Medical Sciences

##### Expected recruitment start date

2007-06-22, 1386/04/01

##### Expected recruitment end date

2008-08-20, 1387/05/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison between cefixime and co-amoxiclavate therapeutic effects in outpatient treatment of acute community acquired pneumonia

##### Public title

Comparison between cefixime and co-amoxiclavate therapeutic effects in outpatient treatment of acute community acquired pneumonia

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: diagnosis of acute community acquired pneumonia; age more than 15 years and capable of giving informed consent. Exclusion criteria: immune deficiency disease or corticosteroids medication; allergy to beta-lactam drugs and weight less than 35 kg

##### Age

From **15 years** old to **85 years** old

##### Gender

Both

##### Phase

N/A

##### Groups that have been masked

*No information*

##### Sample size

Target sample size: **310**

### **Randomization (investigator's opinion)**

Randomized

### **Randomization description**

### **Blinding (investigator's opinion)**

Triple 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 Arak university of medical sciences

##### **Street address**

Arak University of Medical Sciences, Alamalhoda st.

##### **City**

Arak

##### **Postal code**

##### **Approval date**

2007-05-23, 1386/03/02

##### **Ethics committee reference number**

89-83-7/1

## **Health conditions studied**

### 1

#### **Description of health condition studied**

Pneumonia

#### **ICD-10 code**

J14

#### **ICD-10 code description**

Pneumonia due to Haemophilus influenzae

## **Primary outcomes**

### 1

#### **Description**

Therapeutic effects

#### **Timepoint**

At the begining, 2th and 4th weeks

#### **Method of measurement**

Clinical examination and chest X ray

## **Secondary outcomes**

### 1

#### **Description**

Pulmonary abscess

#### **Timepoint**

Second and 4th weeks

#### **Method of measurement**

Clinical examination and chest X ray

### 2

#### **Description**

pulmonary empyema

#### **Timepoint**

2TH,4TH WEEKS

#### **Method of measurement**

clinical examination and CXR

### 3

#### **Description**

Pleural effusion

#### **Timepoint**

Second and 4th weeks

#### **Method of measurement**

Clinical examination and chest X ray

## **Intervention groups**

### 1

#### **Description**

Intervention group: Cefixime 400mg/day + 2 placebo capsules for 2 weeks

#### **Category**

Treatment - Drugs

### 2

#### **Description**

Control group: Co-amoxiclave 625mg/tds for 2 weeks

#### **Category**

Treatment - Drugs

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Valiasr hospital clinic

##### **Full name of responsible person**

##### **Street address**

##### **City**

Arak

### 2

#### **Recruitment center**

##### **Name of recruitment center**

Alavi clinic

##### **Full name of responsible person**

##### **Street address**

**City**  
Arak

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Vice Chancellor for Research, Arak University of Medical Sciences

**Full name of responsible person**

Dr.Saeed Changizi Ashtiyani

**Street address**

Arak University of Medical Sciences, Sardasht st.

**City**

Arak

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Vice Chancellor for Research, Arak 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**

Arak University of Medical Sciences

**Full name of responsible person**

Dr. Nader Zarinfar

**Position**

Infectious disease specialist

**Other areas of specialty/work**

**Street address**

Arak University of Medical Sciences, Valiasr hospital

**City**

Arak

**Postal code**

**Phone**

+98 86 1223 5605

**Fax**

**Email**

zarinfar@arakmu.ac.ir

**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Dr. Nader Zarinfar

**Position**

Infectious disease specialist

**Other areas of specialty/work**

**Street address**

Arak University of Medical Sciences. Valiasr hospital

**City**

Arak

**Postal code**

**Phone**

+98 86 1223 5605

**Fax**

**Email**

zarinfar@arakmu.ac.ir; daesmaili@gmail.com

**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Dr. Akram Esmaili

**Position**

MD

**Other areas of specialty/work**

**Street address**

Arak University of Medical Sciences

**City**

Arak

**Postal code**

**Phone**

**Fax**

**Email**

daesmaili@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*