

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)

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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 beginning, 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

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Full name of responsible person

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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