Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

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

Public title

Comparison between cefixime and co-amoxiclave 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 than15 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 capsuls 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
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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