Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Clinical trial for evaluation of effect of procalcitonin-based algorithm in duration of antibiotic therapy and hospitalization of community acquired pneumonia and chronic obstructive pulmonary disease exacerbation

Protocol summary

Summary

The use of biomarkers in diagnostic and therapeutic approach to community acquired pneumonia (CAP) has been attended. The aim of this study is that whether using the procalcitonin (PCT) algorithm can reduce treatment duration and hospitalization in CAP without change in clinical outcomes or not. This reduction results in decrease of hospital and patient cost and antibiotic resistance. In this double blind randomized clinical trial study, 140 hospitalized patients in Infectious ward of Arak Valiasr hospital with diagnosis of pneumonia are enrolled to the study and randomly divided into two groups, case (PCT-guided therapy) and control group (common treatment). Major inclusion criteria are: diagnosis of community acquired pneumonia or chronic obstructive pulmonary disease exacerbation with at least one respiratory symptom, in addition to at least one respiratory sign on auscultation or one infection indicator. Major exclusion criteria are: Patients that can not consent voluntary, active IV drug users, severe immunosuppression, severe comorbidity, patients with hospital- acquired pneumonia and patients requiring antibiotic therapy for chronic infection. All patients would have 14 days follow up. Patient characteristics such as sex, age, place of residence, cigarette smoking, comorbidities and primary symptoms are recorded. Moreover clinical signs, radiologic and laboratory evaluation are performed and recorded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017010331737N1**
Registration date: **2017-02-24, 1395/12/06**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2017-02-24, 1395/12/06

Registrant information

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Arak University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Arak University of Medical Sciences

Expected recruitment start date

2015-05-12, 1394/02/22

Expected recruitment end date

2016-02-11, 1394/11/22

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial for evaluation of effect of procalcitonin-based algorithm in duration of antibiotic therapy and hospitalization of community acquired pneumonia and chronic obstructive pulmonary disease exacerbation

Public title

Use of Procalcitonin in therapy of Pneumonia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients to be at least 18 years; with diagnosis of Community Acquired Pneumonia (CAP) or Chronic Obstructive Pulmonary Disease (COPD) exacerbation; with at least one respiratory symptom (cough, sputum, dyspnea, tachypnea, pleuretic chest pain); in addition to at least one respiratory sign on auscultation (rales,cripitation); or one infection indicator (T greater than 38 c, chills, WBC less than 4000 or greater than 10000 per milliliter); hospitalized in Infectious ward of Arak Valiasr University Hospital. Exclusion criteria: Patients that can't consent voluntary; active IV drug users; severe immunosuppression (except use of corticosteroid); severe comorbidity; patients with hospital- acquired pneumonia (pneumonia presented at 48 hours after hospitalization or previous history of hospitalization during 14 days before this admission); patients requiring antibiotic therapy for chronic infection.

Age

From **18 years** old to **100 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **140**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Arak University of Medical Sciences

Street address

A'lam-Al-Hoda Street, Shahid Shiroodi Street, Arak, Markazi Province, Iran

City

Arak

Postal code

3819693345

Approval date

2015-05-11, 1394/02/21

Ethics committee reference number

ir.arakmu.rec.1394.23

Health conditions studied

1

Description of health condition studied

Chronic obstructive pulmonary disease

ICD-10 code

J44.1

ICD-10 code description

Chronic obstructive pulmonary disease with acute exacerbation, unspecified

2

Description of health condition studied

Pneumonia

ICD-10 code

J18.9

ICD-10 code description

Pneumonia, unspecified

Primary outcomes

1

Description

Duration of hospitalization

Timepoint

14 days after intervention

Method of measurement

day

2

Description

Duration of treatment

Timepoint

14 days after intervention

Method of measurement

day

Secondary outcomes

1

Description

Clinical Results

Timepoint

3, 5, 7, 14 days after intervention

Method of measurement

Clinical assessment

Intervention groups

1

Description

In the case group, the antibiotic therapy is guided by serum procalcitonin. In this group, the patients are classified into four groups, according to the procalcitonin algorithm that is validated in previous studies. A procalcitonin level of less than 0.1g/L suggested the absence of bacterial infection and the initiation or continuation of antibiotics is strongly discouraged. A procalcitonin level between 0.1 and 0.25 g/L indicated that bacterial infection is unlikely, and the initiation or continuation of antibiotics is discouraged. A procalcitonin level from 0.25 to 0.5 g/L is considered to indicate a possible bacterial infection and the initiation or continuation of antibiotic therapy is encouraged. A procalcitonin level greater than 0.5 g/L strongly suggested the presence of bacterial infection and antibiotic treatment and continuation is strongly encouraged. Reassessment of procalcitonin is done in procalcitonin group at 3, 5, and 7 days if antibiotic therapy initiated and antibiotics are discontinued on the cutoffs defined above.

Category

Treatment - Other

2

Description

In the control group, the antibiotic therapy is chosen on the basis of usual practice guidelines.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr educational and therapeutic hospital of Arak

Full name of responsible person

Street address

City

Arak

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr. Alireza Kamali

Street address

Anesthesiology Department, Valiasr Hospital, Valiasr Square, Arak

City

Arak

Grant name

Grant code / Reference number

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

Yes

Title of funding source

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

School of Medicine, Arak University of Medical Sciences

Full name of responsible person

Naghmeh Arkan

Position

PhD Student of Infectious Diseases

Other areas of specialty/work

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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