Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Effects of additive therapy of losaretan in chronic obstructive pulmonary disease

Protocol summary

Summary

To evaluate the additive effects of losaretan in treatment of chronic obstructive lung disease. 45 patients, as treatment group, received losartan and 45 patients, as control group, received placebo for 4 months. Patients were evaluated based on spirometry and dyspnea severity index and hematocrit before and after treatment. Inclusion criteria: history of chronic obstructive lung disease base on spirometry data and clinical sign and symptoms referred by pulmonologist. Exclusion criteria: congestive heart failure; renal failure; myocardial infarction in 6monthes ego; consumption of angiotensine converting enzyme inhibitors and angitensine receptors blockers; dehydration; renal artery stenosis; hyperkalemia; uncontrolled hypertension; allergy to losaretan.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201103166080N1**
Registration date: **2012-03-09, 1390/12/19**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2012-03-09, 1390/12/19

Registrant information

Name
Seied Hesamodin Tabaei
Name of organization / entity
Arak university of medical sciences
Country
Iran (Islamic Republic of)
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+98 86 1412 0489
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dr.htaba@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Arak University of medical sciences

Expected recruitment start date

2011-04-21, 1390/02/01

Expected recruitment end date

2012-01-20, 1390/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of additive therapy of losaretan in chronic obstructive pulmonary disease

Public title

Effects of additive therapy of losaretan in chronic obstructive pulmonary disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: history of chronic obstructive lung disease base on spirometry data and clinical sign and symptoms referred by pulmonologist. Exclusion criteria: congestive heart failure; myocardial infarction in 6 months ego; consumption of angiotensine converting enzyme inhibitors and angiotensine receptor blockers; dehydration; renal artery stenosis; hyperkalemia; uncontrolled hypertension; allergy to losaretan.

Age

From **35 years** old to **85 years** old

Gender

Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double 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
Pardis educational site, Bassije square, Sardasht
City
Arak
Postal code
3848176941
Approval date
2011-02-24, 1389/12/05
Ethics committee reference number
89-101-4

Health conditions studied

1

Description of health condition studied
chronic obstructive pulmonary disease
ICD-10 code
J44
ICD-10 code description
Other chronic obstructive pulmonary disease

Primary outcomes

1

Description
FVC-percent of forced vital capacity
Timepoint
4months
Method of measurement
By spirometer

2

Description
FEV1—Forced expiratory volume in one second percent of
Timepoint
4 month
Method of measurement
By spirometr

3

Description
Hematocrit
Timepoint
4 month
Method of measurement
Percent and by coulter sysmex

4

Description
Fev1/fvc
Timepoint
4 months
Method of measurement
By spirometer

5

Description
FEF25%-75%
Timepoint
4months
Method of measurement
By spirometer

6

Description
Severity of dyspnea
Timepoint
4 months
Method of measurement
Grade and by modified medical research council-MMRC Scale

Secondary outcomes

1

Description
Raising of creatinine
Timepoint
1 month
Method of measurement
laboratory

Intervention groups

1

Description

Treatment group: 12.5 milligram losaretan, twice daily for 1 months, and if it is tolerated and creatinine does not raise, it is continuing with 25 milligram for 3 months.

Category

Treatment - Drugs

2

Description

Control group: placebo, twice daily for 4 months

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Amiralmomenin hospital

Full name of responsible person

Dr Mehdi Bakhtiar

Street address

Amiralmomenin, Sardasht

City

Arak

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak university of medical sciences

Full name of responsible person

Dr Said Changizi Ashtiany

Street address

Department of education and Research, University of medical sciences, Pardis site, Bassije square

City

Arak

Grant name

پژوهشی

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

Arak University of medical sciences

Full name of responsible person

Dr. Mehdi Bakhtiar

Position

Internal medicine specialist, pulmonologist

Other areas of specialty/work

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Position

Internal medicine resident

Other areas of specialty/work

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Email

Dr.htaba@arakmu.ac.ir

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