Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison effect of inhalant corticosteroid after 3 months in patient with COPD with eosinophilia and without it that confer to pulmonology clinic of Zahedan university of medical science in 1397

Protocol summary

Study aim
Comparison effect of inhalant corticosteroid after 3 months in patient with COPD with eosinophilia and without it that confer to pulmonology clinic of Zahedan university of medical science in 1397

Design
Randomized sampling from patient that confer to zahedan pulmonologis clinics in 1397

Settings and conduct
for sampling we gut a PBS from all patient, patient insert in one of two group with eosinophilia or without it according PBS results. all patient done 6MWT(patient walk 30 meter distance for 6 minute, during test they can rest if they need) at first visit and after 3 month treatment with inhaler corticosteroids. according this test we can evaluatedapproximate quality of life and effect of our treatment on it.

Participants/Inclusion and exclusion criteria
Inclusion criteria:new patient with COPD diagnosis according history and spiromerty data, that was without exacerbation during last 4 weeks. exclusion criteria:En cardiovascular disease, collagen vascular disease, hematologic-oncologic disorder, copd exacerbation during last 4 weeks, use of corticosteroid for ohter cause

Intervention groups
Patients with COPD that was grouping in eosinophilic or without it, and gut ICS

Main outcome variables
meter of distance that patient walked before and after treatment

General information

Reason for update

Acronym
ندارد

IRCT registration information
IRCT registration number: **IRCT20181126041758N1**
Registration date: **2019-01-19, 1397/10/29**
Registration timing: **retrospective**

Last update: **2019-01-19, 1397/10/29**
Update count: **0**

Registration date
2019-01-19, 1397/10/29

Registrant information

Name
omolbanin afroushte

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 54 3332 2436

Email address
afroushte@zaums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-11-22, 1396/09/01

Expected recruitment end date
2018-07-22, 1397/04/31

Actual recruitment start date
2017-12-18, 1396/09/27

Actual recruitment end date
2018-10-10, 1397/07/18

Trial completion date
2018-10-22, 1397/07/30

Scientific title
Comparison effect of inhalant corticosteroid after 3 months in patient with COPD with eosinophilia and without it that confer to pulmonology clinic of Zahedan

university of medical science in 1397

Public title
Effect of inhaler corticosteroid in chronic lung disease
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
New patient with COPD diagnosis according history and spiromerty data, that was without exacerbation during last 4 week,
Exclusion criteria:
Cardiovascular disease Hematologic-oncologic disorder Collagen vascular disease COPD exacerbation during last 4 weeks Use of corticosteroid for ohter cause parasitic infection
Age
No age limit
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **65**
Actual sample size reached: **59**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Other
Other design features
Both groups got same drug for 3 months, and was recoreded result before and after of receiving drug.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Zahedan university of medical science
Street address
Zahedan university of medical science, Dr Hesabi squere
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9816743463
Approval date
2018-08-14, 1397/05/23
Ethics committee reference number
IR.ZAUMS.REC.1397.224

Health conditions studied

1

Description of health condition studied
Chronic Obstructive Pulmonary Disease
ICD-10 code
J44.9
ICD-10 code description
Chronic obstructive pulmonary disease, unspecified

Primary outcomes

1

Description
Change the distance traveled within 6 minutes on a 30-meter interval after 3 months use of inhalation corticosteroids
Timepoint
At first visit and after 3 month
Method of measurement
6 minute walking test

Secondary outcomes

empty

Intervention groups

1

Description
intervention group: Patient with eosinophilia
Category
Treatment - Drugs

2

Description
Intervention group: Patient without eosinophilia
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Zahedan pulmonologist clinic
Full name of responsible person
Omolbanin Afroushte
Street address
No 20, Golha Ave, Jomhouri Blv
City
Zahedan

Province
Sistan-va-Balouchestan
Postal code
9816986493
Phone
+98 45 3332 2436
Email
o.afroushte@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Zahedan University of Medical Sciences
Full name of responsible person
Dr Nourmohamad Bakhshani
Street address
Zahedan university of medical science, Dr Hesabi square
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9816743463
Phone
+98 54 3329 5784
Email
it@zaums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Zahedan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Zahedan University of Medical Sciences
Full name of responsible person
Omolbanin Afroushte
Position
Internal medicine resident
Latest degree
Medical doctor
Other areas of specialty/work
Internal Medicine
Street address
No 20, Golha Ave, Jomhouri Blv
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
98169986493
Phone
+98 54 3332 2436
Email
O.afroushte@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Zahedan University of Medical Sciences
Full name of responsible person
Omolbanin Afroushte
Position
Internal medicine resident
Latest degree
Medical doctor
Other areas of specialty/work
Internal Medicine
Street address
No 20, Golha Ave, Jomhouri Blv
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9816986493
Phone
+98 54 3332 2436
Email
o.afroushte@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Zahedan University of Medical Sciences
Full name of responsible person
Omolbanin Afroushte
Position
Internal medicine resident
Latest degree
Medical doctor
Other areas of specialty/work
Internal Medicine
Street address
No 20, Golha Ave, Jomhouri Blv
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
Data of 6 minute walking test before and after treatment
When the data will become available and for how long
1 year after publication of article
To whom data/document is available
All medical students
Under which criteria data/document could be used
For same and complementary study
From where data/document is obtainable
Research center of Zaums
What processes are involved for a request to access data/document
Visit to Research Center of Zahedan University of Medical Sciences
Comments
none