

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jul 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 evaluated approximate 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 spirometry 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 other 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 spirometry 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 other 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 recorded 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 square

**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, Jomhuri Blv

**City**

Zahedan

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9816986493  
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+98 45 3332 2436  
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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  
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Sistan-va-Balouchestan  
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+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  
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## Person responsible for scientific inquiries

#### Contact

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## Person responsible for updating data

#### Contact

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**Full name of responsible person**  
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Medical doctor  
**Other areas of specialty/work**  
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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