Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effect of montelukast on the serum levels of inflammatory factors in patients with chronic obstructive pulmonary disease (COPD) in intervention and control groups

Protocol summary

Study aim
The aim of this study was to assess the effect of montelukast on the serum level of inflammatory factors in patients with chronic obstructive pulmonary disease.

Design
Clinical trial with a control group with parallel groups, not blinded and not randomized.

Settings and conduct
Patients will be examined from May 2018 to September 2018 at Shahid Rahimi Hospital in Khorramabad. Patients are randomly divided into two groups. The first group will receive Monte-Lucas and the second group will receive the placebo for 2 months. Blood samples are taken from patients and inflammatory factors such as TNF, CRP, and IL-18 are measured. During the study, doctors and all patients are blind.

Participants/Inclusion and exclusion criteria
Patients with chronic obstructive pulmonary disease, aged 40-70 years, and in stage II-III-IV disease, with stable conditions in the last trimester were considered as the study group, and patients with a history of hospitalization, long-term corticosteroid consumption, another inflammatory diseases, cardiovascular disease, rheumatoid arthritis, lung and liver disease were not studied.

Intervention groups
In one cycle of treatment the patients receives 10 mg of montelukast once a day for two months. In addition in control group will use similar placebo.

Main outcome variables
serum levels of common inflammatory factors such as TNF-α, CRP and IL-18 in COPD patients.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190423043361N1**
Registration date: **2019-08-26, 1398/06/04**
Registration timing: **retrospective**

Last update: **2019-08-26, 1398/06/04**
Update count: **0**

Registration date
2019-08-26, 1398/06/04

Registrant information

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Nazanin Kordalivand
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source

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

Expected recruitment end date
2018-03-21, 1397/01/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of montelukast on the serum levels of inflammatory factors in patients with chronic obstructive

pulmonary disease (COPD) in intervention and control groups

Public title
Montelukast effect in patients with chronic obstructive pulmonary disease
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
COPD patients aged 40 to 70 years Patients with stable conditions in the last trimester Patients who are at stages II-III-IV of the disease
Exclusion criteria:
History of hospitalization History of long-term Corticosteroid use Other inflammatory diseases such as cardiovascular, rheumatic, pulmonary, and liver disease
Age
From **40 years** old to **70 years** old
Gender
Both

Phase
4
Groups that have been masked
No information
Sample size
Target sample size: **74**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Not 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 lorestan University of Medical Sciences
Street address
Shahid Anooshirvan Rezaie Square, University of Medical Sciences, Moallem street, Khorramabad, Lorestan
City
khorramabad
Province
Lorestan
Postal code
6813833946
Approval date
2017-08-02, 1396/05/11
Ethics committee reference number
IR.LUMS.REC.1396.321

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
TNF-α level
Timepoint
60 days
Method of measurement
ELISA Diagnostic Kits

2

Description
level of IL-18
Timepoint
60 days
Method of measurement
ELISA Diagnostic Kits

3

Description
levels of CRP
Timepoint
60 days
Method of measurement
semiquantitative C-reactive protein latex agglutination kit

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In one cycle of treatment the patients receives 10 mg of montelukast, Poursina factory production, once a day for two months.
Category
Treatment - Drugs

2

Description
Control group: The same placebo, Poursina factory production, take one times per day, for 2 month
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Rahimi hospital
Full name of responsible person
Alireza Azargoon
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Sponsors / Funding sources

1

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Khoram-Abad 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
Khoram-Abad University of Medical Sciences
Full name of responsible person
Alireza Azargoon
Position
Associate professor
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be 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