

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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- $\alpha$ , 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

##### Name

Nazanin Kordalivand

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 66 3330 5324

##### Email address

nazanin.kordalivand97@gmail.com

#### 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

khorrabad

##### 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- $\alpha$  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

##### Street address

Shahid Rahimi Hospital, Mojahedin Eslam Street, Khorramabad, Lorestan

##### City

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##### Province

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##### Postal code

6813833946

##### Phone

+98 66 3312 0239

##### Email

nazanin.kordalivand97@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Khoram-Abad University of Medical Sciences

##### Full name of responsible person

Morovat Taheri kalani

##### Street address

khorrabad

##### City

Shahid Anooshirvan Rezaie Square, Moallem street, Khorramabad

##### Province

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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

##### Latest degree

Subspecialist

##### Other areas of specialty/work

Internal Medicine

##### Street address

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Khoram-Abad University of Medical Sciences

##### Full name of responsible person

Alireza Azargoon

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Associate professor

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**Person responsible for updating data****Contact****Name of organization / entity**

Khoram-Abad University of Medical Sciences

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**Position**

Medical doctor

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Internal Medicine

**Street address**

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**Phone**

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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