

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 May 2026

Evaluation of the effect of Montelukast drug in improving the clinical condition of patients with COVID-19 in referral hospitals in Isfahan

Protocol summary

Study aim

Evaluation to the effect of Montelukast on treatment of the patients with COVID-19 infection.

Design

This is a clinical trial in phase 3 in which the patients with diagnosis of COVID-19 will be enrolled in two intervention and control groups in parallel groups. The study will be a randomized double blind one; and the selected patients will be enrolled in quadruple blocks in which there will be 2 intervention and 2 control patients. The patients will be selected with mild, moderate and sever disease. In every group 20 patients (10 patients in intervention and 10 patients in control groups respectively) will be evaluated.

Settings and conduct

This study will be conducted on patients which are admitted in collegiate hospitals, in Iran- Isfahan and the patients with COVID-19 will be enrolled in this study. After randomization , in intervention group; Montelukast 10 mg daily for 14 days will be administered in addition to standard therapy and in control group only standard therapy will be administered. The physician and the patients will not be informed about the kind of therapy.

Participants/Inclusion and exclusion criteria

Every patient with diagnosis of COVID-19 which may be with mild, moderate and/or sever disease will be enrolled in the study. On the other hand the patients who has not complete consent and compliance for study and follow up of them is not possible; then they will not be enrolled. In addition the patients with age below 15 years and the patients who consume Rifampin and Phenobarbital also will not enrolled in the study .

Intervention groups

The patients will be situated in two groups. In intervention group Montelukast will be administered in addition to standard therapy and in control group only standard treatment.

Main outcome variables

Clinical condition, blood O2 saturation, respiratory rate and fever

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181208041886N3**

Registration date: **2020-12-22, 1399/10/02**

Registration timing: **registered_while_recruiting**

Last update: **2020-12-22, 1399/10/02**

Update count: **0**

Registration date

2020-12-22, 1399/10/02

Registrant information

Name

Morteza Pourahmad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3322 0197

Email address

mortezapourahmad@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-21, 1399/10/01

Expected recruitment end date

2021-05-22, 1400/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of Montelukast drug in improving the clinical condition of patients with COVID-19 in referral hospitals in Isfahan

Public title

The effect of Montelukast on COVID 19 disease activity

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Every patient with diagnosis of COVID-19 Mild, moderate and severe stage of the disease

Exclusion criteria:

No complete consent and compliance of the patient for study Follow up of the patient not be possible The age below 15 years old Rifampin and Phenobarbital consumers

Age

From **15 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

At first 15 block will be designed and these blocks, will be divided to 3 groups as the mild (blocks 1 to 5 for patients with mild disease), moderate (blocks 6 to 10 for patients with moderate disease) and severe blocks (blocks 11 to 15 for patients with severe disease). After this designation in every block 4 blank will be designed for the patients as below: Blank 1: Intervention by drug (Montelukast) Blank 2: No intervention by the drug Blank 3: Intervention by the drug (Montelukast) Blank 4: No intervention by the drug In approach to every patient (out patient and/or inpatient) at first he/she will be selected on the inclusion and exclusion criteria and after getting informed consent he/she will be classified as the patient with mild, moderate and severe disease. Then the patient will be placed in the empty blank in his/her own block and will and /or will not take the drug (Montelukast) as the previous designation.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study the patients and the physician who evaluate the signs and symptoms of the patients are blinded about the therapy. To prevent of the bias the montelukast tablet will be give the patients accompanied with other drugs. on the other hand the assessor also will not be informed about the drugs of the patients.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Isfahan University of Medical Sciences

Street address

Sofeh Street

City

Isfahan

Province

Isfahan

Postal code

8189111491

Approval date

2020-08-09, 1399/05/19

Ethics committee reference number

IR.MUI.MED.REC.1399.382

Health conditions studied**1****Description of health condition studied**

COVID-19

ICD-10 code

U07.1

ICD-10 code description

COVID-19, virus identified

Primary outcomes**1****Description**

Discontinuation of fever

Timepoint

Daily till 14 days

Method of measurement

Measurement of temperature by digital infrared thermometer, and the O2 saturation by pulseoximeter.

2**Description**

Decreased Respiratory Rate

Timepoint

Daily till 14 days

Method of measurement

Measurement of fever by a thermometer, and O2 saturation by pulse Oximetry.

3

Description

Decreased Cough

Timepoint

Daily till 14 days.

Method of measurement

Body temperature by thermometer, O2 sat by pulseoximetry.

4

Description

Evaluation of blood O2 Saturation

Timepoint

Daily till 14 days

Method of measurement

Physician evaluation by Puls oxymetry

Secondary outcomes

1

Description

Improvement of the patient with diagnosis of COVID-19 infection

Timepoint

Daily till 14 days

Method of measurement

Evaluation by Physician

Intervention groups

1

Description

Intervention group: the patients with diagnosis of COVID-19 will be treated by tablet Montelukast 10 mg. This treatment will be in addition to standard therapies for these patients. The drug is in tablet and oral form which will be administered once a day and for 14 days. We will use Airokast tablet which is made by Dr. Abidi pharmaceutical company in Iran.

Category

Treatment - Drugs

2

Description

Control group: the patient with diagnosis of COVID-19 will give the standard therapies and without Montelukast.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra Hospital

Full name of responsible person

Morteza Pourahmad

Street address

Sofeh street

City

Isfahan

Province

Isfahan

Postal code

8189111491

Phone

+98 31 3322 0996

Email

mortezapourahmad@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Abidi Pharmaceutical company

Full name of responsible person

Seyed Amir Razavian Ardehali

Street address

Doctor Abidi street

City

Karaj

Province

Alborz

Postal code

1389776363

Phone

+98 21 4450 0229

Email

info@abidipharma.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Abidi Pharmaceutical company

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Industry

Person responsible for general inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Morteza Pourahmad

Position

Professor of infectious diseases

Latest degree

Specialist

Other areas of specialty/work

Infectious diseases

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

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+98 31 3322 0996

Email

Mortezapourahmad@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Morteza Pourahmad

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

the article from this study will be distributed about the effect of Montelukast in treatment of the patients with COVID-19 infection.

When the data will become available and for how long

immediately after article publish

To whom data/document is available

Every body

Under which criteria data/document could be used

No condition except the conditions of the publisher

From where data/document is obtainable

the article which will be published

What processes are involved for a request to access data/document

the procedure which will be prescribed by the publisher

Comments

No comment