Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Nov 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)

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+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 compliace 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 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 sever 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 sever 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
Isfehan
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 termometer, and O2 saturation by pulse Oximetery.

3

Description
Decreased Cough
Timepoint
Daily till 14 days.
Method of measurement
Body temperature by thermometer, O2 sat by pulseoximetery.

4

Description
Evaluation of blood O2 Saturation
Timepoint
Daily till 14 days
Method of measurement
Physician evaluation by Puls oxymetery

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
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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
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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
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Person responsible for updating data

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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