

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

24 Sep 2021

### Effect of Montelukast on inflammatory factors in patients with COVID-19

#### Protocol summary

##### Study aim

1. Detection effect of Montelukast on disease improvement and inflammatory factors in patients with COVID-19  
2. Detection effect of Montelukast on duration of hospitalization, changes of interleukin 1 and 6 levels in serum, cough, and oxygen saturation level

##### Design

Two arm parallel groups randomized trial with blinded care and outcome assessment. Randomization: 2 groups A & B

##### Settings and conduct

The current study will carry in Ayatollah Rohani hospital - Babol-Iran during 2020. All patients will give standard treatment of COVID-19 disease but test group will take Montelukast (Airokast, Abidi) at dose 10mg per day for at least 10 days along with standard regimen. blood sample will collect at beginning and end of study. The demographic data, fever, cough, and oxygen saturation will record. biochemical and inflammation markers such as CBC,CRP,LDH, ESR, ALB, TNF $\alpha$ , IL-1, and IL-6 in serum will measure by kits. Lung ct-scan and duration of hospitalization will record.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 1-All hospitalized patients with confirmed COVID-19 at both gender and 18-90 ages include in this study  
2-All hospitalized patients with confirmed COVID-19 without other severe disease  
3-Patient consent  
Exclusion criteria: 1-Patients with suspected COVID-19  
2-History of allergy to Montelukast  
3-lack of cooperation from the patient

##### Intervention groups

114 patients with COVID-19 will divide two groups (57 patients each group): group1: standard regimen; group2: standard regimen+ Montelukast

##### Main outcome variables

Primary outcomes: CBC,CRP,LDH, ESR, ALB, IL-1,IL-6

#### General information

##### Reason for update

##### Acronym

MLK

##### IRCT registration information

IRCT registration number: **IRCT20180624040213N2**

Registration date: **2020-09-14, 1399/06/24**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-09-14, 1399/06/24**

Update count: **0**

##### Registration date

2020-09-14, 1399/06/24

##### Registrant information

###### Name

Hossein Najafzadehvarzi

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 11 3247 6421

###### Email address

h.najafzadeh@mubabol.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-07-21, 1399/04/31

##### Expected recruitment end date

2021-03-20, 1399/12/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of Montelukast on inflammatory factors in patients with COVID-19

##### Public title

Montelukast in COVID-19

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

All hospitalized patients with confirmed COVID-19 at both gender and 18-90 ages include in this study All hospitalized patients with confirmed COVID-19 without other severe disease Patient consent

### Exclusion criteria:

Patients with suspected COVID-19 History of allergy to Montelukast lack of cooperation from the patient

## Age

From **18 years** old to **90 years** old

## Gender

Both

## Phase

3

## Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

## Sample size

Target sample size: **114**

## Randomization (investigator's opinion)

Randomized

## Randomization description

blocking Randomization & Concealment (A&B groups)

## Blinding (investigator's opinion)

Single blinded

## Blinding description

Blinding: single blind and open label

## Placebo

Not used

## Assignment

Parallel

## Other design features

-

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Babol University of Medical Sciences

##### Street address

Babol University of Medical Sciences, Ganjafrooz street, Kargar squer, Babol

##### City

Babol

##### Province

Mazandaran

##### Postal code

4774547176

## Approval date

2020-07-01, 1399/04/11

## Ethics committee reference number

IR.MUBABOL.REC.1399.222

## Health conditions studied

### 1

#### Description of health condition studied

Covid-19

#### ICD-10 code

U07.1

#### ICD-10 code description

Covid-19 disease

## Primary outcomes

### 1

#### Description

Change of interleukin levels

#### Timepoint

Beging of study and 10 days later

#### Method of measurement

With ELISA kit

## Secondary outcomes

### 1

#### Description

Fever

#### Timepoint

During of study (10 days)

#### Method of measurement

Scoring (mild, moderate, sever)

### 2

#### Description

Cough

#### Timepoint

During of study (10 days)

#### Method of measurement

Scoring (mild, moderate, sever)

### 3

#### Description

Blood oxygen saturation

#### Timepoint

During of study (10 days)

#### Method of measurement

Percentage of blood oxygen

## Intervention groups

### 1

#### Description

Test group: treatment with standard regimen along with Montelukast (current drugs for COVID-19 treatment such as Caletra and supportive treatment+ Montelukast at dose 10mg per day for at least 10 days)

**Category**

Treatment - Drugs

**2**

**Description**

Control group: standard regimen of COVID-19((current drugs for COVID-19 treatment such as Caletra and supportive treatment)

**Category**

Treatment - Drugs

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Ayatollah Rohani hospital

**Full name of responsible person**

Hossein Najafzadehvarzi

**Street address**

Babol University of Medical Sciences, Ganjafrooz street, Kargar squer, Babol

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+98 11 3219 9936

**Email**

najafzadehvarzi@gmail.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Babol University of Medical Sciences

**Full name of responsible person**

Reza Ghadimi

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Babol university of medical sciences, Ganjafrooz street, Kargar squer, Babol

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rezaghadimi@yahoo.com

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Babol 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**

Babol University of Medical Sciences

**Full name of responsible person**

Hossein Najafzadehvarzi

**Position**

Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Medical Pharmacy

**Street address**

Medical faculty, Babol University of Medical Sciences, Ganjafrooz street, Kargar squer, Babol

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**Person responsible for scientific inquiries**

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

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**Email**

**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is 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**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

Primary data will present

**When the data will become available and for how long**

6 months after publication

**To whom data/document is available**

Data will be available for scientific and academic proposes

**Under which criteria data/document could be used**

Data will take for scientific proposes by an allowance of the medical sciences university of Babol.

**From where data/document is obtainable**

Return to the medical sciences university of Babol.

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

Data will take by an allowance of the medical sciences university of Babol.

**Comments**