

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

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 α , 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

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

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najafzadehvarzi@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Reza Ghadimi

Street address

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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

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

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Hossein Najafzadehvarzi

Position

Professor

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Person responsible for updating data

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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