Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 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, coughو and oxygen saturation will record . biochemical and inflammation markers such as CBC,CRP,LDH, ESR, ALB, TNFα, 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 وESR و ALB و 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

City

Babol

Province

Mazandaran

Postal code

4774547176

Phone

+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

Street address

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

City

Babol

Province

Mazandaran

Postal code

4774547176

Phone

+98 11 3219 9936

Email

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

City

Babol

Province

Mazandaran

Postal code

4774547176

Phone

+98 11 3219 9936

Email

najafzadehvarzi@gmail.com

Person responsible for scientific 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

City
Babol
Province
Mazandaran
Postal code
4774547176
Phone
+98 11 3219 9936
Email
najafzadehvarzi@gmail.com

Person responsible for updating data

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
City
Babol
Province
Mazandaran
Postal code
4774547176
Phone
+98 11 3219 9936
Email
najafzadehvarzi@gmail.com

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