

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

The effect of Bromelain and Montelukast on Clinical and non-Clinical parameters in Covid-19 patients

Protocol summary

Study aim

Evaluation of changes in CRP levels, serum lymphocyte levels and inflammatory factors and clinical factors including cough, fever and shortness of breath (oxygenation of cure) in patients with Covid-19 under treatment with oral Bromelain and Montelukast

Design

This study was following oral administration of Bromelain and Montelukast separately and concomitantly in patients with Covid-19 accepted in the emergency department of Hospital. In this study, which is performed in phase 0 of the clinical trial, 60 patients with Covid-19 accidentally (Based on client code number and patient code tracking) were divided into three control groups (20) and sample 1 (20).) And samples 2 (20) were divided.

Settings and conduct

This project will be implemented in Masih Daneshvari Hospital in Tehran.

Participants/Inclusion and exclusion criteria

Infected patients with coronavirus new virus referred to the hospital emergency department

Intervention groups

In group 1 (20 patients), patients were prescribed one Anaheal capsule containing 200 mg of Bromelain every 8 hours (one hour before or after a meal). In group 2 (20 patients), one Anaheal capsule containing 200 mg of Bromelain every 8 hours (one hour before or after a meal) and one Montelukast 10 mg tablet 1 hour before or after dinner were given to patients. Was designated. In the control group (20 patients), the placebo capsule was used at exactly the same intervals.

Main outcome variables

Inflammatory factors, immunological factors

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150725023332N3**

Registration date: **2020-06-27, 1399/04/07**

Registration timing: **registered_while_recruiting**

Last update: **2020-06-27, 1399/04/07**

Update count: **0**

Registration date

2020-06-27, 1399/04/07

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2283 1058

Email address

alirezajahangiri@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-20, 1399/02/01

Expected recruitment end date

2020-09-21, 1399/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Bromelain and Montelukast on Clinical and non-Clinical parameters in Covid-19 patients

Public title

The effect of Bromelain and Montelukast in Covid-19

patients

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Infection with coronavirus is new
Exclusion criteria:
History of severe liver disease History of severe respiratory disorders BMI <12

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: 60

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization was performed in a simple and individual manner with emphasis on the case file of the referring patients and using a table of random numbers. In this method, all patients were coded and randomly assigned the code of each disease to a group.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahid Beheshti University of Medical Sciences, Masih Daneshvari Hospital

Street address

7th Floor, Bldg No.2 SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran.

City

Tehran

Province

Tehran

Postal code

1985717434

Approval date

2020-04-14, 1399/01/26

Ethics committee reference number

IR.SBMU.NRITLD.REC.1399.060

Health conditions studied

1

Description of health condition studied

SARS-COV-2

ICD-10 code

B34.2

ICD-10 code description

Coronavirus infection, unspecified

Primary outcomes

1

Description

Changes in lymphocyte levels

Timepoint

Before intervention , 1 hour later, 6 hours later and 12 hours after the intervention

Method of measurement

Biochemical and immunological tests

2

Description

CRP

Timepoint

Before intervention , 1 hour later, 6 hours later and 12 hours after the intervention

Method of measurement

Biochemical test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In group 1, an Anaheal capsule (Parmon Amin Health Company) containing 200 mg of Bromelain was given to patients every 8 hours (one hour before or after a meal).

Category

Treatment - Drugs

2

Description

Intervention group: In Group 2, an Anahil capsule (Parmon Amin Health Company) containing 200 mg of Bromelain was given to patients every 8 hours (one hour before or after a meal) and a 10 mg montelukast tablet 1 hour before or after dinner.

Category

Treatment - Drugs

3

Description

Control group: In the control group, placebo capsules were used exactly at the above intervals

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Masih Daneshvari Hospital

Full name of responsible person

Alireza Jahangirifard

Street address

Masih Daneshvari Hospital, Darabad Avenue, Shahid Bahonar roundabout

City

Tehran

Province

Tehran

Postal code

1956944413

Phone

+98 21 2610 5050

Email

alirezajahangiri@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

Street address

7th Floor, Bldg No.2 SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran.

City

Tehran

Province

Tehran

Postal code

1956944413

Phone

+98 21 2243 9781

Email

zarghi@sbmu.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Alireza Jahangirifard

Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

Street address

Masih Daneshvari Hospital, Darabad Avenue, Shahid Bahonar roundabout

City

Tehran

Province

Tehran

Postal code

1956944413

Phone

+98 21 2610 5050

Email

alirezajahangiri@sbmu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Behrooz Farzanegan

Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

Street address

Masih Daneshvari Hospital, Darabad Avenue, Shahid Bahonar roundabout

City

Tehran

Province

Tehran

Postal code

1956944413

Phone

+98 21 2610 5050

Email

farzaneganbehrooz@gmail.com

1956944413

Phone

+98 21 2610 5050

Email

b.mirtajani@theaasm.org

Person responsible for updating data**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Seyed Bashir Mirtajani

Position

Research Director

Latest degree

Ph.D.

Other areas of specialty/work

Medical Genetics

Street address

Masih Daneshvari Hospital, Darabad Avenue, Shahid
Bahonar roundabout

City

Tehran

Province

Tehran

Postal code**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable