

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 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**

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**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.

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**Province**

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**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

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### 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**

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**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

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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