# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

02 Nov 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 Qovid-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 Couvid-19 accepted in the emergency department of Hospital. In this study, which is performed in phase 0 of the clinical trial, 60 patients with Quaid 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
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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**

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**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
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## Sponsors / Funding sources

**1**

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**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**
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## Person responsible for updating data

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## 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