# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

18 Sep 2026

## A Randomized, Double-blind, Placebo-controlled study to Evaluate the Efficacy and Safety of the Bromelain, Curcumin and Epigallocatechin in the treatment of outpatient Covid-19 patients

## Protocol summary


**Study aim**

evaluation of the effects of Bromelain, Curcumin and Epigallocatechin in the treatment of outpatient Covid-19 infection.

**Design**

300 Covid-19 positive patients over 18 year old referred to infectious disease clinic enter the case or control group. After adjusting for age, sex, underlying disease and chest CT scan, patients are divided randomly to receive the main or placebo agent in a double blind manner.

**Settings and conduct**

After obtaining informed consent and Explanation for patients referred to the Urmia Tadbir clinic divide into case or control groups. The intervention group will be prescribed 2 tablets (Bromelain, Curcumin and Epigallocatechin) daily for 5 days, 12 hours along with standard treatment as add on therapy. The placebo group will receive 2 placebo tablets daily for 5 days, 12 hours along with standard treatment as add on therapy. All patients will be followed every day or until the occurrence of hospitalization or death by phone call. Finally the duration and severity of symptoms and the frequency of adverse events will be compared between two groups.

**Participants/Inclusion and exclusion criteria**

Inclusion criteria: Patients with Covid-19 over 18 years
Exclusion criteria: history of allergies to green tea, pineapple, latex, turmeric, gastric ulcer in the last 6 months, active bleeding, pregnancy, hepatic or renal failure, coagulation disease, autoimmune disease, gallstones, need of hospitalization

**Intervention groups**

The intervention group will receive 2 capsules, each capsule containing Bromelain, Curcumin, Epigallocatechin daily for 5 days, 12 hours along with standard treatment. Control group will receive 2 placebo tablets for 5 days, 12 hours along with standard treatment.

**Main outcome variables**

Blood oxygen saturation, sense of smell, sense of taste, fever, lung involvement, cough, muscle pain, weakness, gastrointestinal symptoms, death, hospitalization


## General information

**Reason for update**

Record the end of the trial

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20210724051971N1**
Registration date: **2021-08-16, 1400/05/25**
Registration timing: **prospective**

Last update: **2021-11-27, 1400/09/06**
Update count: **1**

**Registration date**

2021-08-16, 1400/05/25

**Registrant information**


**Name**

mahsa behnemoon

**Name of organization / entity**

**Country**

Iran (Islamic Republic of)

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**Email address**

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**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2021-08-18, 1400/05/27

**Expected recruitment end date**
2021-09-09, 1400/06/18
**Actual recruitment start date**
2021-08-22, 1400/05/31
**Actual recruitment end date**
2021-09-16, 1400/06/25
**Trial completion date**
2021-10-13, 1400/07/21

**Scientific title**
A Randomized, Double-blind, Placebo-controlled study to Evaluate the Efficacy and Safety of the Bromelain, Curcumin and Epigallocatechin in the treatment of outpatient Covid-19 patients

**Public title**
Effect of Bromelain , Curcumin and Epigallocatechin in the treatment of outpatient Covid-19 patients
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
New 2019 Corona-virus infection (COVID-19) confirmed by rt-PCR test referred to an outpatient clinic Aged over 18 years
**Exclusion criteria:**
severe infection needing hospitalization according to the diagnosis of infectious disease specialist History of allergies to green tea, pineapple, latex and turmeric history of peptic ulcer in the last 6 months active bleeding (except for menstrual period ) hepatic or renal failure coagulopathies autoimmune disease pregnancy cholelithiasis administration of anti platelet or anticoagulant agents (except aspirin)
**Age**
From **18 years** old
**Gender**
Both

**Phase**
3
**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

**Sample size**
Target sample size: **300**
Actual sample size reached: **300**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
Randomization of patients will be done by the researcher using Excel software. Randomization will be done by creating blocks. The blocks will be considered in sizes of 4 people. Drugs and placebo are packed in similar envelopes and receive a unique 4-digit code. Then for each block there is a box containing 2 packs of drug and 2 packs of placebo (the packs have a code and the researchers do not know the type of drug) is considered that the packages are randomly distributed among the patients of each block.
**Blinding (investigator's opinion)**
Double blinded
**Blinding description**
Patients, physicians and researchers who provide the drug are unaware of its contents because of the same packaging, appearance, taste, color, and instructions on the drugs, but the code on the drug will be different. The codes on the medicine are random. The codes and the type of drug is on a sheet that is sealed in the envelope and the envelope will be opened after the research is completed. The patient data collector and the statistical partner of the project also do not know the type of intervention. Due to the fact that in the control group, placebo is used, which is similar in appearance, taste, color and label to the intervened drug, therefore, patients will be unaware of the type of drug received.
**Placebo**
Used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Research Ethics Committees of Urmia University of Medical Sciences
**Street address**
Resalat st, Orjans Al, urmia university of medical sciences
**City**
Urmia
**Province**
West Azarbaijan
**Postal code**
5714783734
**Approval date**
2021-05-26, 1400/03/05
**Ethics committee reference number**
IR.UMSU.REC.1400.087

## Health conditions studied

### 1

**Description of health condition studied**
Covid 19
**ICD-10 code**
J12.81
**ICD-10 code description**
Pneumonia due to SARS-associated coronavirus

## Primary outcomes

### 1

**Description**
Oxygen saturation
**Timepoint**
Up to two weeks after intervention
**Method of measurement**
Pulse oximetery

### 2

**Description**
Body temperature
**Timepoint**
Up to two weeks after intervention
**Method of measurement**
Thermometer

### 3

**Description**
Cough severity
**Timepoint**
Up to two weeks after intervention
**Method of measurement**
Clinical manifestations of the patient with a score of 1 to 10 depending on the cough severity

### 4

**Description**
Myalgia
**Timepoint**
Up to two weeks after intervention
**Method of measurement**
Phone call, or visit by person in cases of symptom aggravation

### 5

**Description**
Gastrointestinal symptoms
**Timepoint**
Up to two weeks after intervention
**Method of measurement**
Phone call, or visit by person in cases of symptom aggravation

### 6

**Description**
Fatigue
**Timepoint**
Up to two weeks after intervention
**Method of measurement**
Phone call, or visit by person in cases of symptom aggravation

### 7

**Description**
sense of smell
**Timepoint**
Up to two weeks after intervention
**Method of measurement**
Phone call, or visit by person in cases of symptom aggravation

### 8

**Description**
sense of taste
**Timepoint**
Up to two weeks after intervention
**Method of measurement**
Phone call, or visit by person in cases of symptom aggravation

## Secondary outcomes

### 1

**Description**
Mortality
**Timepoint**
Up to one month after intervention
**Method of measurement**
Phone call, and clinical follow up

### 2

**Description**
Hospitalization
**Timepoint**
Up to one month after intervention
**Method of measurement**
Phone call, and clinical follow up

### 3

**Description**
lung involvement
**Timepoint**
Up to two weeks after intervention
**Method of measurement**
Phone call, and clinical follow up

## Intervention groups

### 1

**Description**
Intervention group: The group receiving 2 drug capsules In addition to standard treatments ( each capsule containing 150 mg Bromelain, 300 mg Curcumin and 50 mg Epigallocatechin ) daily at intervals of 12 hours during the day for 5 days
**Category**
Treatment - Drugs

### 2

**Description**

Control group: The group receiving the 2 placebo capsules in addition to standard treatments daily at intervals of 12 hours during the day for 5 days

**Category**
Placebo

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**
Tadbir clinic, Urmia, Iran

**Full name of responsible person**
Mahsa Behnemoon

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Ammar st, Urmia, Iran

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## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**
Oroumia University of Medical Sciences

**Full name of responsible person**
Iraj Mohebbi

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Orjhans Street, Resalat Blvd, Urmia

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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**
Oroumia 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**
Oroumia University of Medical Sciences

**Full name of responsible person**
Mahsa Behnemoon

**Position**
Assistant professor

**Latest degree**
Specialist

**Other areas of specialty/work**
Cardiology

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No. 17, 2nd alley, Soltani Ave., Varzesh street, Urmia,Iran

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## Person responsible for scientific inquiries

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**Latest degree**
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## Person responsible for updating data

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**Position**
Assistant professor

**Latest degree**
Specialist

**Other areas of specialty/work**
Cardiology

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## 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**
All data is potentially shareable after unidentified patients

**When the data will become available and for how long**
Access period start 1 month after publishing the results

**To whom data/document is available**
University professors, clinical specialists, researchers, and journals

**Under which criteria data/document could be used**
Official request from organization

**From where data/document is obtainable**
Person responsible for scientific inquiries

**What processes are involved for a request to access data/document**
Request to Vice-Chancellor for Research and Technology Affairs in Urmia university of medical science

**Comments**