

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)

Phone

+98 44 3343 4393

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)

AgeFrom **18 years** old**Gender**

Both

Phase

3

Groups that have been masked

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

Sample sizeTarget 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

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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 oximetry

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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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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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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Person responsible for updating data

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Latest degree

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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