Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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)
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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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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Medical Student

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Person responsible for updating data

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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