Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Jun 2026

Investigating the effect of bromelain on inflammatory and immunological indicators of patients with covid-19

Protocol summary

Study aim
Investigating the effect of bromelain on inflammatory and immunological indicators of patients with covid-19

Design
A clinical trial with a control group, parallel groups, phase 3, double-blind, and randomized on 100 patients. Randomization by random numbers table.

Settings and conduct
The present study will be a randomized clinical trial, and the tested population will be among patients infected with the new coronavirus referred to Masih Deneshvari Hospital in Tehran. Considering the inclusion criteria, patients are randomly divided into two groups. In the sample group, one Anahil capsule containing 500 mg of bromelain is prescribed to the patients every 12 hours. In the control group, placebo capsules are used exactly with the above intervals. Peripheral blood samples are taken from all patients in regular appointments according to the attached questionnaire and sent to the laboratory to check the investigated factors. The results are evaluated based on the design of the questionnaire and its completion, using the t-test and SPSS21 software.

Participants/Inclusion and exclusion criteria
Inclusion criteria: aged between 18-70 years, patient being alert. Exclusion criteria: lack of consent to enter the project, allergy to pineapple and bromelain drug, hospitalization in ICU, suffering from liver and kidney diseases, use of corticosteroids in the last two weeks.

Intervention groups
In the intervention group, one Anahil capsule containing 500 mg of bromelain was prescribed to the patients every 12 hours. In the control group, placebo capsules were used with the above intervals.

Main outcome variables
WBC; lymph; Neutrophil; ESR; CRP; IL-6; TNFa

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20150725023332N6**
Registration date: **2023-02-28, 1401/12/09**
Registration timing: **retrospective**

Last update: **2023-02-28, 1401/12/09**
Update count: **0**

Registration date
2023-02-28, 1401/12/09

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
2021-09-22, 1400/06/31

Expected recruitment end date
2022-03-21, 1401/01/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effect of bromelain on inflammatory and immunological indicators of patients with covid-19

Public title

Investigating the effect of bromelain in patients with covid-19

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18-70 years Patient consciousness Consent to enter the study

Exclusion criteria:

kidney and liver diseases corticosteroid uses in the last two weeks sensitivity to pineapple and bromelain drug hospitalization in ICU

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

- Investigator
- Data analyser

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

With simple randomization and using random numbers table and individual randomization unit. For randomization, we use a table that consists of random digits from 0 to 9. Each of the figures in this table is repeated the same on average. There is no discernible pattern of numerical values. In this method, each figure is assigned to a treatment group. We start from the first row of the table and move down row by row. For two treatments, we put numbers 0 to 4 for treatment A and numbers 5 to 9 for treatment B. The numbers in the first row of the table are as follows: 0,5,2,7,8,4,3,7,..... Now, based on the above numbers, we have the following allocation for people: A, B, A, B, B, ...

Blinding (investigator's opinion)

Double blinded

Blinding description

In order to prevent any possible complications, the main therapist is aware of the assignment of treatment groups. The patients participating in the study were not blinded to the treatment they received. The experts responsible for data collection and analysis are not aware of the allocation of different study groups.

Placebo

Not 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

Street address

Next to Ayatollah Taleghani Hospital, Shahid Arabi Street

City

Tehran

Province

Tehran

Postal code

198396-3113

Approval date

2022-01-30, 1400/11/10

Ethics committee reference number

IR.SBMU.RETECH.REC.1400.864

Health conditions studied

1

Description of health condition studied

COVID-19

ICD-10 code

U07.02

ICD-10 code description

COVID-19, virus identified

Primary outcomes

1

Description

WBC

Timepoint

Before and after receiving the drug

Method of measurement

Cell counting

2

Description

The number of lymphocytes

Timepoint

Before and after receiving the drug

Method of measurement

Cell counting

3

Description

The number of neutrophils

Timepoint

Before and after receiving the drug

Method of measurement

Cell counting

4

Description

ESR

Timepoint

Before and after receiving the drug

Method of measurement

Sadiman Reader

5

Description

CRP

Timepoint

Before and after receiving the drug

Method of measurement

Biochemical test

6

Description

IL-6

Timepoint

Before and after receiving the drug

Method of measurement

Biochemical test

7

Description

TNFa

Timepoint

Before and after receiving the drug

Method of measurement

Biochemical test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients receive one Anahil capsule containing 500 mg of bromelain every 12 hours.

Category

Treatment - Drugs

2

Description

Control group: patients receive one placebo capsule every 12 hours.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Masih Daneshvari Hospital

Full name of responsible person

Alireza Jahangirifard

Street address

Masih Daneshvari Hospital, Daar Abad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

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Shahid Beheshti University of Medical Sciences and Medical Services, next to Taleghani Hospital, Yemen Street

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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
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Person responsible for scientific inquiries

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Shahid Beheshti University of Medical Sciences
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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
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available