

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

The effect of propolis supplementation on clinical symptoms in patients with coronavirus (COVID-19): A randomized, double-blind, placebo-controlled clinical trial

Protocol summary

Study aim

This clinical trial aims to assess the effect of propolis on clinical symptoms in patients with coronavirus.

Design

This study is a double-blind, placebo-controlled, randomized phase 2 clinical trial evaluating the effect of propolis on clinical symptoms in patients with coronavirus. In this study, 80 eligible participants will be randomly assigned to either the intervention or the control group. The randomization sequence will be generated using a random-number table.

Settings and conduct

In this study, patients with coronavirus will be recruited from the Al-Zahra hospital in Isfahan. Participants who meet entry criteria will be randomly assigned to the propolis group or the placebo group. The participant's assignment will be concealed from all participants and investigators, with the exception of the study pharmacist.

Participants/Inclusion and exclusion criteria

The inclusion criteria are the age of 18 to 75 years, willingness to participate with written informed consent, and the diagnosis of coronavirus based on the PCR test. The exclusion criteria are the current use of warfarin, current use of propolis supplement, and presence of sensitivity to bee products.

Intervention groups

Participants in the intervention group will receive an identical propolis tablet (containing 300 mg Iranian green propolis extract) three times a day for 2 weeks. Participants in the placebo group will receive an identical tablet placebo (containing 300 mg microcrystalline cellulose) three times a day for 2 weeks.

Main outcome variables

Respiratory Rate, Chest CT scan, High-sensitivity C-reactive protein, Erythrocyte Sedimentation Rate, Severity and number of coughs

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200802048267N1**

Registration date: **2020-10-20, 1399/07/29**

Registration timing: **registered_while_recruiting**

Last update: **2020-10-20, 1399/07/29**

Update count: **0**

Registration date

2020-10-20, 1399/07/29

Registrant information

Name

Karim Sohrabi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3822 2003

Email address

sohrabi@mail.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-08-22, 1399/06/01

Expected recruitment end date

2021-03-21, 1400/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of propolis supplementation on clinical symptoms in patients with coronavirus (COVID-19): A randomized, double-blind, placebo-controlled clinical trial

Public title

Propolis supplementation AND Coronavirus

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

A willing to participate with written informed consent The diagnosis of coronavirus based on the PCR test.

Exclusion criteria:

Current use of warfarin Current use of Propolis Supplement Presence of sensitivity to bee products

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Eligible participants will be randomly assigned to either the propolis group or the placebo group. Randomization will be performed in a 1:1 ratio with the use of block sizes of 4, with stratification according to the gender. Randomization sequences will be prepared by the study pharmacist with the use of a random number table.

Blinding (investigator's opinion)

Double blinded

Blinding description

Assignment of participants to the study groups will be concealed from participants and investigators, with the exception of the study pharmacist and care provider, until the end of the study and data analysis. The study pharmacist who will be aware of the assignments will be prepared the placebo tablets similar to the propolis tablet in color, odor, taste, shape, size, and weight. Drug containers will be the same in terms of shape, color, odor, size, and weight and will be kept inside numbered, opaque, and sealed envelopes which will be completely impermeable to light.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Hezarjarib Ave., Isfahan University of Medical Sciences

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2020-07-29, 1399/05/08

Ethics committee reference number

کمیته اخلاق دانشگاه علوم پزشکی اصفهان
IR.MUI.MED.REC.1399.337

Health conditions studied

1

Description of health condition studied

covid 19

ICD-10 code

U07.1

ICD-10 code description

Covid-19

Primary outcomes

1

Description

Respiratory Rate

Timepoint

day 1 and day 14

Method of measurement

The number of breaths a person takes per minute

2

Description

Chest CT scan

Timepoint

Day 1 and day 14

Method of measurement

X ray imaging

3

Description

High-sensitivity C-reactive protein

Timepoint

Day 1 and day 14

Method of measurement

Colorimetric method

4

Description

Erythrocyte Sedimentation Rate

Timepoint

Day 1 and day 14

Method of measurement

Colorimetric method

5

Description

Severity and number of coughs

Timepoint

Day 1 and day 14

Method of measurement

Cough visual analogue scale (VAS)

Secondary outcomes

1

Description

Body temperature

Timepoint

Day 1 and day 14

Method of measurement

Clinical Thermometer

2

Description

Alanine aminotransferase Activity

Timepoint

Day 1 and day 14

Method of measurement

Colorimetric method

3

Description

Aspartate aminotransferase Activity

Timepoint

Day 1 and day 14

Method of measurement

Colorimetric method

4

Description

Superoxide dismutase Activity

Timepoint

Day 1 and day 14

Method of measurement

Colorimetric method

5

Description

Albumin

Timepoint

Day 1 and day 14

Method of measurement

Colorimetric method

Intervention groups

1

Description

Intervention group: Participants in the intervention group will receive an identical propolis tablet (containing 300 mg Iranian green propolis) three times a day, before breakfast, lunch, and dinner, for 2 weeks. All tablets are prepared by the Reyhan Naghsh Jahan Pharmaceutical Co., Isfahan, Iran.

Category

Treatment - Drugs

2

Description

Control group: Participants in the control group will receive an identical placebo tablet (300 mg microcrystalline cellulose) three times a day, before breakfast, lunch, and dinner, for 2 weeks. All tablets are prepared by the Reyhan Naghsh Jahan Pharmaceutical Co., Isfahan, Iran.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra Hospital

Full name of responsible person

Karim Sohrabi

Street address

Alzahra Hospital, Soffeh Avenue, Isfahan

City

Isfahan

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Isfahan

Postal code

8174675731

Phone

+98 31 3822 2003

Email

sohrabi@mail.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjooy

Street address

Hezar Jarib Ave, Isfahan University of Medical Sciences

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Province

Isfahan

Postal code

8174673461

Phone

+98 31 3668 8138

Email

sh_haghjoo@med.mui.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

Vice-Chancellor for Research, Esfahan University of Medical Sciences

Proportion provided by this source

50

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**

Esfahan University of Medical Sciences

Full name of responsible person

Karim Sohrabi

Position

Hospital Manager

Latest degree

Specialist

Other areas of specialty/work

Emergency Medicine

Street address

Alzahra Hospital, Soffeh Avenue, Isfahan

City

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Postal code

8174675731

Phone

+98 31 3822 2003

Email

sohrabi@mail.mui.ac.ir

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Karim Sohrabi

Position

Hospital Manager

Latest degree

Specialist

Other areas of specialty/work

Emergency Medicine

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Person responsible for updating data**Contact****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Karim Sohrabi

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Emergency Medicine

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Phone

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Email

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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

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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The non-identifiable individual participant data collected in this study will be shared. Also, The protocol, results, and statistical analysis of the current study will be published in the relevant articles.

When the data will become available and for how long

The non-identifiable individual participant data will become available after the publication of the relevant

articles.

To whom data/document is available

The non-identifiable individual participant data will become available to other researchers in academic institutions.

Under which criteria data/document could be used

The non-identifiable individual participant data can only be used for research.

From where data/document is obtainable

The non-identifiable individual participant data will be obtainable by sending an e-mail to Mr. Karim Sohrabi (Email: sohrabi@mail.mui.ac.ir).

What processes are involved for a request to access data/document

Other researchers in academic institutions can send their request by e-mail to Mr. Karim Sohrabi (Email: sohrabi@mail.mui.ac.ir). The data will be sent to them after consulting and approving the research team.

Comments