Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Oct 2021

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
Isfehan

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
Province
Isfehan
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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Isfehan
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
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Isfahan
Province
Isfehan
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
Street address
Alzahra Hospital, Soffeh Avenue, Isfahan
City
Isfahan
Province
Isfehan
Postal code
8174675731
Phone
+98 31 3822 2003
Email
sohrabi@mail.mui.ac.ir

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
Street address
Alzahra Hospital, Soffeh Avenue, Isfahan
City
Isfahan
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Isfehan
Postal code
8174675731
Phone
+98 31 3822 2003
Email
sohrabi@mail.mui.ac.ir

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