

# 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

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

##### **Province**

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

**City**

Isfahan

**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

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**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**

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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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**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**