Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

The effect of propolis supplementation on clinical manifestations and inflammatory biomarkers in patients with COVID-19

Protocol summary

Study aim
Determination The effect of propolis supplementation on clinical manifestations and inflammatory biomarkers in patients with COVID-19

Design
Clinical trial with control group, with parallel groups, triple blind, randomized, phase 3 on 88 patients. The randomization will be based on the order of the randomization table prepared by the computer

Settings and conduct
This clinical trial will be performed on 88 patients with Covid-19 referring to the clinic of Razi Hospital in Ahvaz. Patients are treated with medication for 4 weeks according to the defined protocol. In order to blind the study, patients, physicians, and researchers are unaware of which group are taking studying drug or placebo.

Participants/Inclusion and exclusion criteria
Patients aged 18 to 65 years Laboratory confirmation of Covid-19 (2019-nCoV Real-Time RT-PCR)

Intervention groups
Patients in both groups receive the treatment based on the fifth version of the Covid-19 National Guidelines.Patients in the intervention group, in addition to the standard treatment protocol, receive propolis supplement in the form of 500 mg capsules twice a day for 1 month. And the control group also receives placebo according to the above method.

Main outcome variables
Cough; Oxygen saturation; Respiratory rate; Body temperature; Ll-6; TNF alpha; Crp-hs; CBC

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200326046868N1**
Registration date: **2020-05-09, 1399/02/20**
Registration timing: **prospective**
Last update: **2020-05-09, 1399/02/20**
Update count: **0**

Registration date
2020-05-09, 1399/02/20

Registrant information

Name
Reza Malihi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 61 5326 7800

Email address
r.malihi@abadanums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-05-21, 1399/03/01

Expected recruitment end date
2020-06-21, 1399/04/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of propolis supplementation on clinical manifestations and inflammatory biomarkers in patients with COVID-19

Public title
effect of propolis in COVID-19

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients aged 18 to 65 years Laboratory confirmation of Covid-19 (2019-nCoV Real-Time RT-PCR)

Exclusion criteria:

Pregnancy and lactation, a history of allergies to honey and bee products, uncontrolled underlying disease including neuropsychiatric problems, diabetes, thyroid disorders, heart disease, chronic liver or kidney failure, and autoimmune diseases.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **88**

Randomization (investigator's opinion)

Randomized

Randomization description

In this triple blind study, patient, physician (treatment team) and the data analyzer did not know the type of data and supplements.Allocate patients to two intervention and control groups so that the list of subjects studied will be randomly generated by a computer.The intervention and control group will be placed inside the numbered envelopes and will be sealed.

Blinding (investigator's opinion)

Triple blinded

Blinding description

In this study patients, Physician and researcher don't know which group of patients will use the medicine placebo.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Abadan School of Medical Sciences

Street address

Abadan School of Medical Sciences,Beginning of the 30 meters Ave, Zolfaghari street, Abadan city.

City

Ahvaz

Province

Khouzestan

Postal code

631911154 061

Approval date

2020-04-26, 1399/02/07

Ethics committee reference number

IR.ABADANUMS.REC.1399.031

Health conditions studied

1

Description of health condition studied

Covid-19

ICD-10 code

U07.1

ICD-10 code description

Other coronavirus as the cause of diseases classified elsewhere

Primary outcomes

1

Description

Cough

Timepoint

First and 30 days after the intervention

Method of measurement

Clinical examination

2

Description

Oxygen saturation

Timepoint

First and 30 days after the intervention

Method of measurement

Clinical examination

3

Description

Respiratory rate

Timepoint

First and 30 days after the intervention

Method of measurement

Clinical examination

4

Description

Body temperature

Timepoint

First and 30 days after the intervention

Method of measurement

Clinical examination

5

Description
LI-6
Timepoint
First and 30 days after the intervention
Method of measurement
ELISA

6

Description
TNF alpha
Timepoint
First and 30 days after the intervention
Method of measurement
ELISA

7

Description
Crp-hs
Timepoint
First and 30 days after the intervention
Method of measurement
ELISA

8

Description
CBC
Timepoint
First and 30 days after the intervention
Method of measurement
Cell counter

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The propolis supplement is taken as a 500 mg capsule twice a day for 1 month
Category
Treatment - Drugs

2

Description
Control group: The placebo is taken as a capsule twice a day for 1 month
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Razi hospital
Full name of responsible person
Reza Malihi
Street address
Razi hospital, Felestin Ave, Amanieh Ave
City
Ahvaz
Province
Khouzestan
Postal code
6155819953
Phone
+98 61 3555 0592
Email
r.malihi@abadanums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Abadan University of Medical Sciences
Full name of responsible person
Sara Mobarak
Street address
Abadan School of Medical Sciences,Beginning of the 30 meters Ave, Zolfaghari street, Abadan city.
City
Abadan
Province
Khouzestan
Postal code
631911154
Phone
+98 61 5338 4004
Email
s.mobarak@abadanums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Abadan 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

Abadan University of Medical Sciences

Full name of responsible person
Reza Malihi

Position
Faculty member

Latest degree
Master

Other areas of specialty/work
Nutrition

Street address
Abadan School of Medical Sciences,Beginning of the 30 meters Ave, Zolfaghari street, Abadan city.

City
Ahvaz

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Person responsible for scientific inquiries

Contact

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Abadan University of Medical Sciences

Full name of responsible person
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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available

Title and more details about the data/document
All potential data can be shared after people have not been identified

When the data will become available and for how long
Since 2021

To whom data/document is available
Researchers working in academic and scientific institutions

Under which criteria data/document could be used
No other conditions are considered

From where data/document is obtainable
Email of Responsible person

What processes are involved for a request to access data/document
1 week after receiving email

Comments