

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Oct 2020

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; LI-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

Khuzestan

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

Khuzestan

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

Khuzestan

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
Province
Khuzestan
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631911154
Phone
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Email
r.malihi@abadanums.ac.ir

Person responsible for scientific 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
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+98 61 5338 4004
Email
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Person responsible for updating data

Contact

Name of organization / entity

Abadan University of Medical Sciences
Full name of responsible person
Reza Malihi
Position
faculty member
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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