Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 2026

Evaluation of the effect of Propolis on the recovery process of COVID 19 patients

Protocol summary

Study aim
Evaluation of the effect of Propolis in the treatment of COVID 19 patients

Design
This clinical trial was performed on 72 patients, divided into two groups of 36, including a control group and parallel groups. This study is Double-blind and block randomization method is used.

Settings and conduct
The field of work is clinical - internal. This study is performed in the Tohid Hospital in Sanandaj. Patients, physicians, and nurses who evaluate the outcomes will be blind to the groups studied.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Confirmed diagnosis of COVID19 with RT-PCR, Hospitalized patients, Ventilator independent patients Exclusion Criteria: Pregnancy, Breastfeeding, Type 1 diabetes, Severe renal failure, Metabolic acidosis, Severe respiratory failure, Chemotherapy recipients, Taking anticoagulants

Intervention groups
Patients in both groups receive the treatment based on the Covid-19 National Guidelines. Patients in the intervention group, in addition to the standard treatment protocol, receive Propolis Capsule in the form of 500mg capsules (made by Shahdineh Golha Company) twice a day for 14 days and the control group also receives placebo according to the above method.

Main outcome variables
Fever, Cough, Muscle pain, Blood oxygen saturation percentage, CRP, CBC, ESR, Respiratory Rate, Heart Rate, CT scan findings, Gastrointestinal symptoms, Anorexia, Loss of Smell and Taste, Shortness of breath, Headache, Sore throat, BMI, IL-6

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190415043279N9**
Registration date: **2020-12-22, 1399/10/02**
Registration timing: **registered_while_recruiting**

Last update: **2020-12-22, 1399/10/02**
Update count: **0**

Registration date
2020-12-22, 1399/10/02

Registrant information

Name
Pezhman Sharifi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 87 3324 9435

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-12-05, 1399/09/15

Expected recruitment end date
2021-04-04, 1400/01/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the effect of Propolis on the recovery process of COVID 19 patients

Public title

Evaluation of the effect of Propolis COVID 19

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Definitive confirmation of Covid 19 based on RT-PCR results Hospitalized patients Ventilator independent patients

Exclusion criteria:

Pregnancy Breastfeeding Type 1 diabetes Severe renal failure Metabolic acidosis Severe respiratory failure Chemotherapy recipients Taking anticoagulants

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

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

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

Using block randomization method with a block size of 4. Sampling method at this study will be according to random allocation. Participants will enter the study according to inclusion criteria, and then will be divided into two groups according to randomization table. One group will receive Propolis Capsule and the other will receive placebo. The participants and administrator do not have any information about content of capsules (double blinded study). The list of randomization was computer-generated. supplements and placebo capsules were placed in completely identical packages and were coded by someone who was unaware of the nature of the study in numbered bottles based on the list. And another person who was unaware of the contents of the pack provided them to the patients.

Blinding (investigator's opinion)

Double blinded

Blinding description

All supplements and placebo capsules were identical with respect to appearance and only differed in coding of the capsules. The treatment code of the intervention supplements was blinded for subjects, investigators and staff involved in the conduct of the study.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kurdistan University of Medical Sciences

Street address

Pasdaran Blvd., Kurdistan University of Medical Sciences

City

Sanandaj

Province

Kurdistan

Postal code

66117713446

Approval date

2020-10-13, 1399/07/22

Ethics committee reference number

IR.MUK.REC.1399.168

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

Fever

Timepoint

At the beginning of the study (before the intervention), days 3, 5, 7 and after the intervention

Method of measurement

Thermometer

2

Description

CBC

Timepoint

At the beginning of the study (before the intervention) and after the intervention

Method of measurement

Cell Counter

3

Description
Cough
Timepoint
At the beginning of the study (before the intervention), days 3, 5, 7 and after the intervention
Method of measurement
Questionnaire

4

Description
Muscle pain
Timepoint
At the beginning of the study (before the intervention), days 3, 5, 7 and after the intervention
Method of measurement
Questionnaire

5

Description
C Reactive Protein
Timepoint
At the beginning of the study (before the intervention) and after the intervention
Method of measurement
Agglutination

6

Description
Blood oxygen saturation percentage
Timepoint
At the beginning of the study (before the intervention), days 3, 5, 7 and after the intervention
Method of measurement
Pulse oximeter

7

Description
Respiratory Rate
Timepoint
At the beginning of the study (before the intervention), days 3, 5, 7 and after the intervention
Method of measurement
By observing the occurrence of breaths

8

Description
Heart Rate
Timepoint
At the beginning of the study (before the intervention), days 3, 5, 7 and after the intervention
Method of measurement
Pulse oximeter

9

Description
Erythrocyte sedimentation rate (ESR)
Timepoint
At the beginning of the study (before the intervention) and after the intervention
Method of measurement
ESR device

10

Description
Lactate Dehydrogenase
Timepoint
At the beginning of the study (before the intervention) and after the intervention
Method of measurement
Autoanalyzer

11

Description
CT scan findings
Timepoint
At the beginning of the study (before the intervention) and after the intervention
Method of measurement
CT scan

12

Description
Gastrointestinal symptoms
Timepoint
At the beginning of the study (before the intervention), days 3, 5, 7 and after the intervention
Method of measurement
Questionnaire

13

Description
Anorexia
Timepoint
At the beginning of the study (before the intervention), days 3, 5, 7 and after the intervention
Method of measurement
Questionnaire

14

Description
Loss of Smell and Taste
Timepoint
At the beginning of the study (before the intervention), days 3, 5, 7 and after the intervention
Method of measurement
Questionnaire

15

Description
Shortness of breath
Timepoint
At the beginning of the study (before the intervention), days 3, 5, 7 and after the intervention

Method of measurement
Questionnaire

16

Description
Headache
Timepoint
At the beginning of the study (before the intervention), days 3, 5, 7 and after the intervention
Method of measurement
Questionnaire

17

Description
Sore throat
Timepoint
At the beginning of the study (before the intervention), days 3, 5, 7 and after the intervention
Method of measurement
Questionnaire

18

Description
Body Mass Index (BMI)
Timepoint
At the beginning of the study (before the intervention) and after the intervention
Method of measurement
by measuring height and weight using a scale and height meter

19

Description
IL-6
Timepoint
At the end of the intervention
Method of measurement
ELISA kit

20

Description
Duration of hospitalization
Timepoint
Daily since hospitalization
Method of measurement
Counting the day

21

Description
Need for ICU
Timepoint
Daily since hospitalization
Method of measurement
Patient's file

22

Description
Need for intubation
Timepoint
Daily since hospitalization
Method of measurement
Patient's file

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Propolis capsules are taken in the form of 500 mg capsules (made by Shahdineh Golha Company) twice a day for 14 days.
Category
Placebo

2

Description
Control group: The placebo is taken as a capsule Twice a day for 14 days.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Tohid Hospital
Full name of responsible person
Dr. Vahid Yousefinejad
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Sanandaj 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
Sanandaj University of Medical Sciences

Full name of responsible person
Vahid Yousefinejad

Position
Assistant professor

Latest degree
Specialist

Other areas of specialty/work
Forensic Medicine

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be 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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available