# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 2026

## The effectiveness comparison of Hyoscyamus niger methanolic extract and propolis in the treatment of patients with covid-19

### Protocol summary

**Study aim**
The effect determination of Hyoscyamus niger-extracted methanolic extract with propolis on blood factors and clinical symptoms in patients with covid-19

**Design**
A clinical trial with a control group, with parallel groups, double-blind, randomized, phase 2 is performed on 90 patients. Patients with terminated block randomization with 4 and 6 blocks are divided into two groups of intervention and placebo.

**Settings and conduct**
The study is performed in hospitalized patients with covid-19. In this study, patients are randomly divided into intervention group including patients receiving the product with routine drugs and placebo group including patients receiving placebo with routine drugs. The treatment will be done in the form of syrup with specific labels during 6 days of study.

**Participants/Inclusion and exclusion criteria**
The status of entry: Patients should be exposed to covid-19. The patient must have a voluntary and consciously consent because to participate in trail. The status of no entry: Patients with heart and mental problems and pregnant women The exit status of study: The dissatisfaction of patient for staying in the study or having side complications impressive on patient's health

**Intervention groups**
The herbal product is given to the patient in syrup form amount 60 CC with specific labels. The patient's daily intake is mount 30 CC per day. The patient receives 10 CC equivalent to one tablespoon of syrup every 8 hours. The syrup is enough for 2 days and the patient will be given new syrups within six days of studying.

**Main outcome variables**
The evaluation of clinical symptoms such as fever, cough, shortness of breath, etc. The assessment of blood factors CBC, ESR and CRP The comparison of heart beat number, blood pressure, body temperature and number of breaths per minute, percentage of blood oxygen saturation and number of days requiring oxygen adjuvant therapy.

### General information

**Reason for update**
Dear Sir/Madam, there were few changes that edited.

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20200516047462N2**
Registration date: **2020-07-17, 1399/04/27**
Registration timing: **registered_while_recruiting**

Last update: **2021-10-05, 1400/07/13**
Update count: **3**

**Registration date**
2020-07-17, 1399/04/27

**Registrant information**

**Name**
morteza kosari

**Name of organization / entity**

**Country**
Iran (Islamic Republic of)

**Phone**
+98 31 5434 6622

**Email address**
yeganehbadi.m@iums.ac.ir

**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2020-07-08, 1399/04/18

**Expected recruitment end date**
2020-12-10, 1399/09/20

**Actual recruitment start date**
empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effectiveness comparison of Hyoscyamus niger methanolic extract and propolis in the treatment of patients with covid-19

**Public title**

The effect of Hyoscyamus niger with propolis on covid-19

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Acute respiratory labeling (ARI) with 2-fold reduction under control: RR> 30; 80% <PO2 <93%; Chest floor Pulmonary infiltration; Clinical judgment of a specialist Age range 18 to 85 years of both sexes The patient does not have any serious concurrent cardiovascular and cerebral diseases The patient's ability and personal desire to fill out a personal consent form to enter the study

**Exclusion criteria:**

History of heart disease, mental disease and pregnant women Existence of any history of allergy to any of the components of the herbal product Nausea and vomiting and intolerance to food Resistant hypoxemia and decreased level of consciousness Hemodynamic instability Hypercapnia - Respiratory fatigue

**Age**

From **18 years** old to **85 years** old

**Gender**

Both

**Phase**

2

**Groups that have been masked**

- Participant
- Investigator

**Sample size**

Target sample size: **140**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Samples are divided into two groups by terminated block randomization method with blocks of 4 and 6, prescription drugs (intervention and placebo) are determined based on this method and a special number is assigned to them.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Physician and patient are unaware of drug or placebo receiving and there are codes that were registered on syrup and only the epidemiologist informs as a plan executor.

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

کمیته اخلاق دانشگاه علوم پزشکی اصفهان

**Street address**

Isfahan University of Medical Sciences, Hezar Jarib Ave, Isfahan Town

**City**

Isfahan

**Province**

Isfehan

**Postal code**

۷۳۴۶۱۸۱۷۴۶

**Approval date**

2020-10-11, 1399/07/20

**Ethics committee reference number**

IR.MUI.MED.REC.1399.595

### 2

**Ethics committee**

**Name of ethics committee**

Ethics committee of Kashan University of Medical Sciences

**Street address**

Ghotb Ravandi Blvd

**City**

Kashan

**Province**

Isfehan

**Postal code**

8715981151

**Approval date**

2020-07-08, 1399/04/18

**Ethics committee reference number**

IR.KAMUS.REC.1399.016

## Health conditions studied

### 1

**Description of health condition studied**

Coronavirus

**ICD-10 code**

U07.1

**ICD-10 code description**

Covid-19

## Primary outcomes

### 1

**Description**

The comparison of the symptoms such as fever, dry cough, diarrhea, vomiting, sore throat, sore throat and

larynx, abdominal pain and chest pain, nausea, chills and anorexia

**Timepoint**

The hypotheses are tested at the beginning of the study and on the second, fourth, and sixth days of treatment

**Method of measurement**

Questionnaire and observation

**2**

**Description**

Comparison of blood factors CBC, ESR and CRP

**Timepoint**

The hypotheses are tested at the beginning of the study and on the second, fourth, and sixth days of treatment

**Method of measurement**

Biochemical factors measured in a clinical laboratory

**3**

**Description**

Comparison of heart rate, blood pressure and body temperature

**Timepoint**

The hypotheses are tested at the beginning of the study and on the second, fourth, and sixth days of treatment

**Method of measurement**

Pressure gauge and thermometer

**4**

**Description**

Comparison of respiration rate per minute, percentage of blood oxygen saturation and number of days requiring adjuvant oxygen therapy

**Timepoint**

The hypotheses are tested at the beginning of the study and on the second, fourth, and sixth days of treatment

**Method of measurement**

Pulse Oximeter

**5**

**Description**

Evaluation of drug side effects

**Timepoint**

Days of the first, second and fourth, sixth days after the start of treatment between the intervention and control groups

**Method of measurement**

View and questionnaire and ...

**6**

**Description**

Comparison of the status of withdrawal from the continuation of the study

**Timepoint**

After starting treatment between the intervention and control groups

**Method of measurement**

View and questionnaire

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**

Intervention group: Herbal product including methanolic extract of seeds and propolis is prepared in the form of 60 cc syrup and this amount of syrup is prepared for two days of the patient and the patient drinks 10 cc of syrup three times a day for six days and each time. Receives. During 6 days of study, three bottles of 60 cc syrup will be provided to the patient.

**Category**

Treatment - Drugs

**2**

**Description**

Control group: Syrup for six days and daily in three times and each time 10 cc of syrup without plant products is given to the patient in the form of ordinary syrup. The syrup in the amount of 60 cc is prepared for the patient for two days and is given to the patient after the syrup is finished. The second and third syrups are given to the patient for consumption during six days of study.

**Category**

Placebo

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**

Shahid Beheshti Hospital, Kashan

**Full name of responsible person**

Mohammad Kazem Sayah

**Street address**

Ghotb Ravandi Blvd, Shahid Beheshti Hospital

**City**

Kashan

**Province**

Isfehan

**Postal code**

87159/81151

**Phone**

+98 31 5554 0026

**Fax**

+98 31 5554 8900

**Email**

beheshtihospital@kaums.ac.ir

**2**

**Recruitment center**

**Name of recruitment center**

Al-Zahra Hospital, Isfahan

**Full name of responsible person**

Morteza Kosari

**Street address**
Al-Zahra Hospital , sofeh Blvd, Shahid Keshvari Highway , IsfahanBlvd, Shahid Keshvari Highway , Isfahan
**City**
Isfahan
**Province**
Isfehan
**Postal code**
8174675731
**Phone**
+98 31 3668 5555
**Email**
alzahra@mui.ac.ir

**3**

**Recruitment center**
**Name of recruitment center**
Isabn-e-Maryam Hospital, Isfahan
**Full name of responsible person**
morteza kosari
**Street address**
Isabn-e-Maryam Hospital ,Shams Abadi St, Isfahan
**City**
Isfahan
**Province**
Isfehan
**Postal code**
8174675742
**Phone**
+98 31 3233 9012
**Email**
st-maryam@mui.ac.ir

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Kashan University of Medical Sciences
**Full name of responsible person**
Dr. Hamidreza Banafsheh
**Street address**
Ghotb Ravandi Blvd ,Kashan University of Medical Sciences
**City**
Kashan
**Province**
Isfehan
**Postal code**
8715988141
**Phone**
+98 31 5554 2999
**Fax**
+98 31 5557 5057
**Email**
research@kaums.ac.ir
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Kashan University of Medical Sciences
**Proportion provided by this source**
10
**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**
Kashan University of Medical Sciences
**Full name of responsible person**
Morteza Kosari
**Position**
Phd student
**Latest degree**
Master
**Other areas of specialty/work**
Physiology
**Street address**
Kashan University of Medical Sciences, Ghotb Ravandi Blvd.
**City**
Kashan
**Province**
Isfehan
**Postal code**
8715988141
**Phone**
+98 31 5554 2999
**Fax**
+98 31 5557 5057
**Email**
research@kaums.ac.ir

## Person responsible for scientific inquiries

**Contact**
**Name of organization / entity**
Kashan University of Medical Sciences
**Full name of responsible person**
Morteza Kosari
**Position**
Phd Student
**Latest degree**
Master
**Other areas of specialty/work**
Physiology
**Street address**
Kashan University of Medical Sciences, Ghotb Ravandi Blvd.

**City**
Kashan
**Province**
Isfehan
**Postal code**
8715988141
**Phone**
+98 31 5554 2999
**Fax**
+98 31 5557 5057
**Email**
research@kaums.ac.ir

## Person responsible for updating data

**Contact**
**Name of organization / entity**
Kashan University of Medical Sciences
**Full name of responsible person**
Morteza Kosari
**Position**
Phd Student
**Latest degree**
Master
**Other areas of specialty/work**
Physiology
**Street address**
Kashan University of Medical Sciences, Ghotb Ravandi Blvd.
**City**
Kashan
**Province**
Isfehan
**Postal code**
8715988141
**Phone**
+98 31 5554 2999
**Fax**
+98 31 5557 5057
**Email**
research@kaums.ac.ir

## 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**
Undecided - It is not yet known if there will be a plan to make this available
**Data Dictionary**
Undecided - It is not yet known if there will be a plan to make this available