

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Oct 2026

The effect of methanolic extract of hyoscyamus niger containing steroidal glycosides with propolis in patients with acute respiratory infection (infection or suspected covid-19): A clinical trials

Protocol summary

Registration timing: **registered_while_recruiting**

Study aim

The effect determination of bergamot seeds-extracted methanolic extract containing steroidal glycosides with propolis for treatment of patients with acute respiratory infection including patients with or suspected of covid-19 into clinical trial

Last update: **2020-05-17, 1399/02/28**

Update count: **0**

Registration date

2020-05-17, 1399/02/28

Design

- The testing process is two-headed blind, meaning that 25 patients receive the product (dried methanolic extract with propolis) and another 25 patients receive placebo. Physician and patient have not information about received medicine and patients receiving placebo are also placebo.

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

Settings and conduct

Outpatients in Kashan Akhavan Clinic and 16-hour centers of Sepehri and Shahid Beheshti Hospital, Kashan University of Medical Sciences, Kashan, Iran

Recruitment status

Recruitment complete

Funding source

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Patients who, in addition to acute respiratory illness. 2. The patient's ability and its personal desire to fill out of personal consent form to enter the study Output Criteria: 1. Pregnancy and lactation 2. Heart and mental patients

Expected recruitment start date

2020-05-06, 1399/02/17

Expected recruitment end date

2020-06-06, 1399/03/17

Intervention groups

Patients with acute respiratory infection (covid-19 suspected or suspected)

Actual recruitment start date

empty

Actual recruitment end date

empty

Main outcome variables

Clinical symptoms include dry cough, shortness of breath, fever and chills.

Trial completion date

empty

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200516047462N1**

Registration date: **2020-05-17, 1399/02/28**

Scientific title

The effect of methanolic extract of hyoscyamus niger containing steroidal glycosides with propolis in patients with acute respiratory infection (infection or suspected covid-19): A clinical trials

Public title

Intervention

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 The patient must have a voluntary consent to participate in operation; The patient's clinical symptoms such as: dry cough, shortness of breath, fever, shortness of breath, fatigue, etc. in suspected or associated with COVID-19 is evaluated after treatment and these symptoms are compared with placebo group.
Exclusion criteria:
 Heart patients, mental patients and pregnant women

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: 50

Randomization (investigator's opinion)
Randomized

Randomization description
 After acceptance and registration, these samples are entered in study by physician and nurse of clinic and also project manager based on the entry and exit criteria. The samples are divided into two groups by method of terminated block randomization with blocks 4 and 6. Prescriptive drugs (intervention and placebo) are determined based on this method with a special number to them. Physician and patient are not aware of intervention type and the patient's assignment to each treatment will be assign randomly.

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

Ethics committee of Kashan University of Medical Sciences

Street address

Ghotb Ravandi Blvd

City

Kashan

Province

Isfahan

Postal code

55578011

Approval date

2020-05-06, 1399/02/17

Ethics committee reference number

IR.KAMUS.REC.1399.001

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

Shortness of breath, medicine, dry cough, chills and etc.

Timepoint

May and June

Method of measurement

Quantitative and qualitative

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Products containing 10 mg of methanolic extract plus 450 mg of propolis will be prescribed three times a day for each patient. This amount of active ingredients is dissolved in 30cc of simple BP syrup. This 30 cc is ordered in 10cc (one tablespoon) every 8. The time will be prescribed. The formulated syrup will be given to the patients in the amount of 60 cc required by the above-mentioned order for 2 days and the patients will go to the clinic every two days after receiving the medicine again, the questionnaire and clinical symptoms will be referred to the clinic. In addition, suspected patients with covid 19 will be delivered to patients after the approval of an infectious disease specialist and, if the patient agrees, and will receive a signature and fingerprint in the syrup

consent form. Prescribing syrup and examining the patient's symptoms are 6 days.

Category

Treatment - Drugs

2

Description

Control group: Simple BP syrup (without therapeutic products) will be prescribed every 10 hours with a 10cc (one tablespoon) recipe. Two days later, the drug will be returned to the clinic, a questionnaire and clinical signs will be sent to the clinic. In addition, suspected patients with covid 19 will be delivered to patients after the approval of an infectious disease specialist and, if the patient agrees, and will receive a signature and fingerprint in the syrup consent form. Prescribing syrup and examining the patient's symptoms are 6 days.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Akhavan Clinic, Sepehri 16-hour Center, Shahid Beheshti Hospital

Full name of responsible person

Morteza Kosari

Street address

Ghotb Ravandi Blvd, Kashan University of Medical Sciences

City

Kashan

Province

Isfahan

Postal code

8715988141

Phone

+98 31 5554 2999

Fax

+98 31 5557 5057

Email

research@kaums.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

City

kashan

Province

Isfahan

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

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

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

No. 16, Hakim Alley. , Montazeri St. , Badrod Town

City

Isfahan

Province

Isfahan

Postal code

8766113894

Phone

+98 31 5434 6622

Email

kosarimorteza12@gmail.com

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
No. 16, Hakim Alley., Montazeri St. , Badrod Town
City
Badrod
Province
Isfahan
Postal code
8766113894
Phone
+98 31 5434 6622
Email
kosarimorteza12@gmail.com

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
No. 16, Hakim Alley. , Montazeri St. , Badrod Town

City
Badrod
Province
Isfahan
Postal code
8766113894
Phone
+98 31 5434 6622
Email
kosarimorteza12@gmail.com

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