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

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

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.

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

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

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

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

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200516047462N1**
Registration date: **2020-05-17, 1399/02/28**
Registration timing: **registered_while_recruiting**

Last update: **2020-05-17, 1399/02/28**
Update count: **0**

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

Registrant information

Name
morteza kosari

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-05-06, 1399/02/17

Expected recruitment end date
2020-06-06, 1399/03/17

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

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

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Kashan

Province

Isfehan

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

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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?

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

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Person responsible for updating data

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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

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