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

Acronym

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

Last update: 2020-07-17, 1399/04/27
Update count: 0

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

Registrant information
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Recruitment status
Recruitment complete

Funding source

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

Expected recruitment end date
2020-08-22, 1399/06/01

Actual recruitment start date
empty
Actual recruitment end 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; 85% <PO2 <93%; Chest floor Pulmonary infiltration; Clinical judgment of a specialist Age range 18 to 75 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 75 years old

Gender
Both

Phase
2

Groups that have been masked
• Participant
• Investigator

Sample size
Target sample size: 90

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

Secondary Ids
empty

Ethics committees
1

Ethics committee
Name of ethics committee
Ethics committee of Kashan University of Medical Sciences

Street address
Kashan University of Medical Sciences, Ghotb Ravandi Blvd.

City
Kashan

Province
Isfahan

Postal code
55578011

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

Recruitment centers

1
Recruitment center
Name of recruitment center
Shahid Beheshti Hospital, Kashan
Full name of responsible person
Mohammad Kazem Sayah
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2
Recruitment center
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3
Recruitment center
Name of recruitment center
Person responsible for general inquiries

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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