Clinical Trial Protocol
Iranian Registry of Clinical Trials
12 Sep 2020

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
Name
morteza kosari
Name of organization / entity
Country
Iran (Islamic Republic of)
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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

**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**
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
Street address
Ghotb Ravandi Blvd, Shahid Beheshti Hospital
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2
Recruitment center
Name of recruitment center
Razi Hospital, Rasht
Full name of responsible person
Morteza Kosari
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3
Recruitment center
Name of recruitment center
### Razi Hospital of Ahvaz

**Full name of responsible person**
Morteza Kosari

**Street address**
Palestine Street, in front of the Governorate, Razi Hospital, Ahvaz Town

**City**
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### Sponsors / Funding sources

1

**Sponsor**

**Name of organization / entity**
Kashan University of Medical Sciences

**Full name of responsible person**
Dr. Hamidreza Banafsheh

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Ghotb Ravandi Blvd, Kashan University of Medical Sciences

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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**
10

**Public or private sector**
Public

**Domestic or foreign origin**
Domestic

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### 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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Latest degree
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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