Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 2026

Evaluating efficacy of Kelofan syrup, a traditional Iranian medicine product on pulmonary & other clinical and laboratory manifestations of patients with or probable of covid-19

Protocol summary

Study aim

Evaluating efficacy of Kelofan syrup on pulmonary & other clinical and laboratory manifestations of patients with probable or confirmed COVID-19

Design

This study is a randomized controlled clinical trial on hospitalized patients with probable or confirmed COVID-19. Individuals with eligibility criteria will be randomly divided into two groups of intervention and control, and 30 patients will be enrolled in each group. The study is three-blinded and the patient, the nurse giving the medication, the data collector, and the data analyzer are not aware of the type of assignment.

Settings and conduct

This study will be carried out at Imam Khomeini Hospital, one of the hospitals affiliated to Ardabil University of Medical Sciences. This hospital has been assigned for COVID-19 patients. This research will be carried out from May to July of 2020.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients over 18 years old hospitalized with or probable of COVID-19 based on Radiological findings or Positive PCR test according to the instructions of the Ministry of Health; Clinically classified as moderate and severe, no need for intubation; written and informed satisfaction of patients Non-inclusion: Liver, kidney and heart failure; History of allergies to medicinal herbs; Immunodeficiency; Uncontrplled Hypertension; Uncontrolled Diabetes; Alcohol or drug addiction

Intervention groups

Patients are receiving a herbal formulation (Kelofan syrup) in form of a syrup at a dose of 7.5 cc two times a day for a maximum of seven days, in addition to standard treatment.

Main outcome variables

Respiratory rate per minute; O2 Saturation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200405046960N2**
Registration date: **2020-05-19, 1399/02/30**
Registration timing: **registered_while_recruiting**

Last update: **2020-05-19, 1399/02/30**
Update count: **0**

Registration date

2020-05-19, 1399/02/30

Registrant information

Name

ramin nasimi doost azgomi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 45 3352 0365

Email address

r.nasimi@arums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-17, 1399/02/28

Expected recruitment end date

2020-07-05, 1399/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Evaluating efficacy of Kelofan syrup, a traditional Iranian medicine product on pulmonary & other clinical and laboratory manifestations of patients with or probable of covid-19

Public title
Efficacy of Kelofan syrup on COVID-19

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients over 18 years old Hospitalized patients withprobable or confirmed COVID-19 based on radiologicalfindings or positive PCR test according to the instructions22of the Ministry of Health Clinically classified as moderateand severe, no need for intubation Written and informedsatisfaction of patients

Exclusion criteria:
Liver, kidney and heart failure History of allergies to medicinal herbs Immunodeficiency Uncontrolled hypertension Uncontrolled diabetes Alcohol or drug addiction Patients with transplanted organs Cor Pulmonel Patients Takinganticoagulants, antiarrhythmics, antihypertensives, corticosteroids and immunosuppressants Pregnancy Breast feeding

Age
From **18 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Samples will be randomly assigned to four blocks using Random Allocation Software. Blocking and allocation sequences for concealment will be done by the non-involved researcher (Allocation Concealment).The sample allocation ratio will be Allocation 1:1 and will be divided into two groups of receiving Iranian medicine products and control group (Assignment). Then based on blocks and allocation sequences medication will be given to patients

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, patients will be informed by consent form that they would either be in the intervention group or the control group, but they won't be aware of the type of medication. Nurses who supply the drug are also unaware of its content because the appearance, taste, color, and prescription of the drug are similar, but the code on the drug will be different. The written codes on the drugs are random and only the non-involved researcher is aware of the drug type and the inserted code on it. The patient data collector and the project statistical partner are also unaware of the type of intervention. As the control group uses placebo, which is similar in appearance, taste, color, and prescription, patients will be unaware of the type of drug being administered.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

1

Registry name

Secondary trial Id

Registration date
empty

Ethics committees

1

Ethics committee

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

Street address
Ardabil University of Medical Sciences; Daneshgah street

City
Ardabil

Province
Ardabil

Postal code
5618985991

Approval date
2020-04-05, 1399/01/17

Ethics committee reference number
IR.ARUMS.REC.1399.009

Health conditions studied

1

Description of health condition studied
Covid-19

ICD-10 code
U07.1

ICD-10 code description
COVID19, virus identified

2

Description of health condition studied
Covid-19

ICD-10 code

U07.2

ICD-10 code description

COVID19, virus not identified

Primary outcomes

1

Description

Oxygen saturation

Timepoint

Clinical examination and Pulse Oximetry before starting intervention and regularly during hospitalized

Method of measurement

Pulse Oximeter

2

Description

Respiratory Rate

Timepoint

Clinical examination before starting intervention and regularly during hospitalized

Method of measurement

Respiratory Count

Secondary outcomes

1

Description

C-reactive protein

Timepoint

Intravenous blood testing before starting intervention and during hospitalized

Method of measurement

Venous blood test

2

Description

Lymphocytes

Timepoint

Intravenous blood testing before starting intervention and during hospitalized

Method of measurement

Venous blood test

3

Description

White Cell blood count

Timepoint

Intravenous blood testing before starting intervention and during hospitalized

Method of measurement

Venous blood test

4

Description

Liver enzymes

Timepoint

Intravenous blood testing before starting intervention and during hospitalized

Method of measurement

Venous blood test

5

Description

Cough

Timepoint

Clinical examination before starting intervention and regularly during treatment

Method of measurement

Patient follow up

6

Description

Fever

Timepoint

Clinical examination before starting intervention and regularly during treatment

Method of measurement

Thermometer

Intervention groups

1

Description

Intervention group: In the intervention group, in addition to the standard treatment, medicinal herbal products will be prescribed.The drug will be given in syrup form. The syrup will contain the following medicinal herbs: Nepeta bracteata، Adiantum capillus veneris، Glycyrrhiza glabra, Foeniculum vulgare، Viola odorata, Ziziphus jujube, Malva sylvestris, Nigella sativa . The intervention group will receive 7.5 cc of Kelofan syrup every 12 hours one week.

Category

Treatment - Drugs

2

Description

Control group: This group receive routine treatments for COVID-19 disease and placebo. Placebo will be given as an oral syrup, two servings a day. For the placebo syrup, of stevia, authorized oral dyes are used to make the color and taste relatively similar to the original drug.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Ramin Nasimi Doost Azgomi

Street address
Emam Khomeini Hospital, Baradaran Shahid Noei Aghdam street

City
Ardabil

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5618985991

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Email
modir7060@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Ardabil University of Medical Sciences

Full name of responsible person
Dr.Shahab Bohloolil

Street address
Ardabil University of Medical Sciences; Daneshgah street

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Phone
+98 45 3353 4776

Email
shahab.bohlooli@arums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Ardabil 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
Ardabil University of Medical Sciences

Full name of responsible person
Ramin Nasimi Doost Azgomi

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Traditional Medicine

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Ardabil University of Medical Sciences

Full name of responsible person
Ramin Nasimi Doost Azgomi

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
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Person responsible for updating data

Contact

Name of organization / entity
Ardabil University of Medical Sciences

Full name of responsible person
Ramin Nasimi Doost Azgomi

Position
Associate professor

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