Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 2026

Evaluating efficacy of Kelofan syrup, a traditional Iranian medicine product, on pulmonary and other clinical and laboratory manifestations of patients with probable or confirmed 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 pilot clinical trial will be performed on 15 hospitalized patients with probable or confirmed COVID-19, as before-after trial without any control group.

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 in April 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; Hypertension; 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: **IRCT20200405046960N1**
Registration date: **2020-04-08, 1399/01/20**
Registration timing: **prospective**

Last update: **2020-04-08, 1399/01/20**
Update count: **0**

Registration date
2020-04-08, 1399/01/20

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
2020-04-09, 1399/01/21

Expected recruitment end date
2020-04-24, 1399/02/05

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 and other clinical and

laboratory manifestations of patients with probable or confirmed 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 with probable or confirmed 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
Exclusion criteria:
Liver, kidney and heart failure History of allergies to medicinal herbs Immunodeficiency Hypertension Diabetes Alcohol or drug addiction Patients with transplanted organs Cor Pulmonel Patients Taking anticoagulants, antiarrhythmics, antihypertensives, corticosteroids and immunosuppressants Pregnancy Breast feeding
Age
From **18 years** old
Gender
Both

Phase
1-2
Groups that have been masked
No information
Sample size
Target sample size: **15**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

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 medication and regularly during treatment
Method of measurement
Pulse Oximeter

2

Description
Respiratory Rate
Timepoint
Clinical examination before starting medication and regularly during treatment
Method of measurement
Respiratory Count

Secondary outcomes

1

Description
C-reactive protein
Timepoint
Intravenous blood testing before starting medication and during treatment
Method of measurement
Venous blood test

2

Description
Lymphocytes
Timepoint
Intravenous blood testing before starting medication and during treatment
Method of measurement
Venous blood test

3

Description
White Cell blood count
Timepoint
Intravenous blood testing before starting medication and during treatment
Method of measurement
Venous blood test

4

Description
Liver enzymes
Timepoint
Intravenous blood testing before starting medication and during treatment
Method of measurement
Venous blood test

Intervention groups

1

Description
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، Glycyrrhi za 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 for one week.
Category
Treatment - Drugs

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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modi7060@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ardabil University of Medical Sciences
Full name of responsible person
Dr.Shahab Bohlooli
Street address
Ardabil University of Medical Sciences; Daneshgah street
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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
Street address

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Person responsible for scientific inquiries

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Associate professor

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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