

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 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*, *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 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

Province

Ardabil

Postal code

5618985991

Phone

+98 45 3142 2529

Email

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

City

Ardabil

Province

Ardabil

Postal code

5618985991

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

Street address

Ardabil University of Medical Sciences; Daneshgah street

City

Ardabil

Province

Ardabil

Postal code

5618985991

Phone

+98 45 3142 2529

Email

modir7060@yahoo.com

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

Traditional Medicine

Street address

Ardabil University of Medical Sciences; Daneshgah street

City

Ardabil

Province

Ardabil

Postal code

5618985991

Phone

+98 45 3142 2529

Email

Modir7060@yahoo.com

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

Ph.D.

Other areas of specialty/work

Traditional Medicine

Street address

Ardabil University of Medical Sciences; Daneshgah street

City

Ardabil

Province

Ardabil

Postal code

5618985991

Phone

+98 45 3142 2529

Email

modir7060@yahoo.com

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