Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

Formulation of two natural products (syrup and solution) and evaluation of their effects in patients with coronavirus disease 2019 (COVID-19): A randomized controlled trial

Protocol summary

Study aim

Formulation of two natural products (syrup and solution) and evaluation of their efficacy and safety in COVID-19 patients

Design

This is a parallel 2-arm randomized, controlled, double-blind, single center study. 70 patients are enrolled and followed for 14 days This study is a multi-center randomized, controlled, double-blind clinical trial with two parallel arms. 150 patients will be enrolled in the study and followed for 10 days.

Settings and conduct

This study will be carried out in some Iran University of Medical Sciences hospitals. In the intervention group, 75 patients with COVID-19, in addition to standard recommended treatment, receive Crostop solution and Croguard syrup three times daily for 10 days. Also, 75 patients in the control group receive only the standard recommended treatment.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 18-65 years old participants who highly suspected or confirmed cases of COVID-19 infection; Exclusion criteria: History of drug allergy Uncontrolled diseases including neuropsychiatric disorders, thyroid disorders, heart disease Pregnancy; Breastfeeding Renal or liver failure

Intervention groups

Intervention group in addition to receiving the standard treatment recommended by the National Committee, will receive Crostop solution 10 cc three times daily and Croguard syrup 30 cc three times daily for 10 days. Patients in the control group will receive only the standard treatment.

Main outcome variables

Significant clinical recovery (composite): Clinical recovery up to 10 days from initiation of study treatment until normalization of fever (≤37.2 °C oral), respiratory rate (≤24/minute on room air), and oxygen saturation (>94% on room air), and alleviation of cough (mild or absent on a patient reported scale), sustained for at least 24 hours.

General information

Reason for update

Full name of the responsible person in the three recruitment centers was changed from Amir Hossein Jamshidi to Nader Tavakoli

Acronym

IRCT registration information

IRCT registration number: **IRCT20200316046792N1**
Registration date: **2020-03-17, 1398/12/27**
Registration timing: **registered_while_recruiting**

Last update: **2020-03-24, 1399/01/05**
Update count: **1**

Registration date

2020-03-17, 1398/12/27

Registrant information

Name
Amir Hossein Jamshidi
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 21 5563 9666
Email address
jamshidi.ah@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-03-16, 1398/12/26

Expected recruitment end date
2020-05-20, 1399/02/31
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Formulation of two natural products (syrup and solution) and evaluation of their effects in patients with coronavirus disease 2019 (COVID-19): A randomized controlled trial

Public title
Effect of herbal syrup and solution in treatment of COVID-19
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Laboratory-confirmed COVID-19 cases (2019-nCoV Real-Time RT-PCR), regardless of the clinical manifestations and history of close contact Both the men and women, aged between 18 to 65 years old Signing informed written consent Highly suspected cases of COVID-19 based on positive findings of chest CT scan
Exclusion criteria:
5 days or more after the onset of illness Pregnancy Breastfeeding History of drug allergy Complicated cases with bacterial infection Patients in recovery phase Critical and severe cases such as ARDS Clinical evidence for respiratory insufficiency at the time of hospitalization (SaO2 ≤90% or PaO2 < 8 kPa) in the patient breathing room air without oxygen therapy Comorbidities (e.g. renal failure, liver failure, CHF, cerebrovascular and cardiovascular major diseases, chronic pulmonary disease, malignancy, endocrine and metabolic diseases, any immunodeficiency disorders such as AIDS, encephalopathy, neuropathy)
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **150**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients will be randomized in a 1:1 ratio into one of the treatment groups and standard of care group using computer generated randomization plan. The date and time of randomization will be recorded. Allocation concealment will be done with the sealed envelope method
Blinding (investigator's opinion)
Double blinded
Blinding description
The treatment assignment will remain unknown until the patient is randomized. Physicians who treat patients and the patients will not be blinded. Radiologists, physicians who assess outcomes and the statistician analyzing the data all will be blinded
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Iran University of Medical Sciences
Street address
Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran, 1449614535, Iran
City
Tehran
Province
Tehran
Postal code
۱۴۴۹۶۱۴۵۳۵
Approval date
2020-03-16, 1398/12/26
Ethics committee reference number
IR.IUMS.REC.1398.1399

Health conditions studied

1

Description of health condition studied
COVID-19
ICD-10 code
U07.1
ICD-10 code description
COVID-19

Primary outcomes

1

Description
Response to the treatment (Significant clinical improvement)
Timepoint
At baseline and on the third, fifth, seventh, and tenth days after starting the treatment

Method of measurement
According to the clinical, paraclinical and laboratory findings. Clinical improvement: normalization of the body temperature (≤37.2 ° C), respiratory rate (≤24 breaths per minute), oxygen saturation (> 94% at room temperature) and cough (zero or mild) that persist for at least 24 hours. Cough will measure on a qualitative scale based on the patient's report . Other outcome variables will measure during clinical examination

2

Description
Complications of the treatment
Timepoint
Daily, until the tenth day
Method of measurement
Interview and patient's record

Secondary outcomes

1

Description
Duration of hospitalization
Timepoint
End of the treatment
Method of measurement
Patient's medical record

2

Description
Mortality
Timepoint
End of the treatment
Method of measurement
Patient's medical record (Clinical outcome)

Intervention groups

1

Description
Intervention group: Hospitalized patients will receive 10 cc Corostop solution and 30 cc Coroguard syrup three times daily for 10 days in addition to receiving standard treatments recommended by the corona county committee.
Category
Treatment - Drugs

2

Description
Control group: Hospitalized patients will receive standard treatment according to the national guidelines for the treatment of COVID-19
Category
Treatment - Drugs

3

Description
Intervention group: Outpatients (self-quarantine at their home) will receive 10 cc Corostop solution and 30 cc Coroguard syrup three times daily for 10 days in addition to receiving standard treatments recommended by the corona county committee.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Firoozgar general hospital
Full name of responsible person
Nader Tavakoli
Street address
Vice-Chancellor’s Office for Treatment, fourth floor, former building of the Ministry of Health and Medical Education, at the Intersection of Jomhuri and Hafez Streets, Tehran
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2

Recruitment center
Name of recruitment center
Hazrate Rasoole Akram Hospital
Full name of responsible person
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Web page address
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3

Recruitment center
Name of recruitment center
Shohadaye Haft-e Tir Hospital
Full name of responsible person
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Web page address
https://iums.ac.ir/en?sid=26

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
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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
Iran 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
Iran University of Medical Sciences
Full name of responsible person
Amir Hossein Jamshidi
Position
Assistant professor
Latest degree
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Other areas of specialty/work
Medical Pharmacy
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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is 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
Title and more details about the data/document
The study results will be published. Also the study protocol and statistical analysis will be considered.
When the data will become available and for how long
One year after completion of the study, data will be published and available
To whom data/document is available
With the financial backing permission, data may be made available to the physicians and academic researchers and institutions.
Under which criteria data/document could be used
Other researchers are permitted to included the results in their systematic reviews and metaanalysis
From where data/document is obtainable
For this you may ask Amirhossein Janshidi through jamshidiam@yahoo.com
What processes are involved for a request to access data/document
After receiving the query, dependent on the requested data, the scientific responsible person of the study will response to the query in coordinate with the sponsor within 2 weeks
Comments