Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Oct 2026

Evaluation of the effect of SINA anti-flu syrup and drop on respiratory quality in COVID-19 ; A double-blind study

Protocol summary

Study aim
Assessment of the effect of Iranian medicine product, SINA anti-flu, on the symptoms of patients with covid-19 (Coronavirus 19 disease)

Design
This clinical trial has control group, and with parallel groups, double blinded, randomized, phase 2 to 3 and is performed on 80 patients. Randomization method will be blocked randomization (Quaternary random blocks).

Settings and conduct
Patients in the drug group take the Iranian traditional drug for ten days and 4 times from syrup and 2 times from drop daily In addition to the usual medicines (According to the protocol of the Ministry of Health). Patient in control group use routine treatment and placebo. The study is performed in Baqiyatallah Hospital.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Male or female patients 18 years old and older with COVID-19, positive coronavirus 19 PCR, Ground glass view at low-dose CT scan, Arterial oxygen saturation less than 93%, Consciously completed consent form completed by the patient or the patient's supervisor. Exclusion criteria: History of pulmonary malignancy, History of asthma or COPD, History of Disabling disease or malignancy, Liver or kidney disorders.

Intervention groups
Intervention groups will be two ones.Patients in the intervention group will receive the intervention drug (syrup & drop) in addition to the routine treatment, but in control group, they will receive placebo in addition to the routine treatment.

Main outcome variables
3D lung CT Scan, dyspnea, cough, arterial oxygen saturation, PCR, CBC diff

General information

Reason for update
changing in email address

Acronym

IRCT registration information
IRCT registration number: **IRCT20160131026298N5**
Registration date: **2020-08-23, 1399/06/02**
Registration timing: **prospective**

Last update: **2025-01-02, 1403/10/13**
Update count: **4**

Registration date
2020-08-23, 1399/06/02

Registrant information

Name
Ahmad Reza Sharifi Olounabadi

Name of organization / entity
Baqiatallah University of Medical Science, Department of Traditional Iranian Medicine

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-09-22, 1399/07/01

Expected recruitment end date
2021-03-19, 1399/12/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Evaluation of the effect of SINA anti-flu syrup and drop on respiratory quality in COVID-19 ; A double-blind study

Public title
Evaluation of the effect of SINA anti-flu natural product on COVID-19
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Male or female patients 18 years old and older with COVID-19 positive coronavirus 19 PCR Ground glass view at low-dose CT scan Arterial oxygen saturation less than 93% Consciously completed consent form completed by the patient or the patient's supervisor
Exclusion criteria:
History of pulmonary malignancy History of asthma or COPD History of Disabling disease or malignancy Liver or kidney disorders
Age
From **18 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization method will be blocked randomization (Blocks of size 4). Randomization units are individuals. Eighty outpatients referred to the hospital emergency department are randomly assigned to one of the two intervention and control groups according to form of random string produced by online random allocation .
Blinding (investigator's opinion)
Double blinded
Blinding description
Study participants, the clinical observer, the data collector, and the data analyzer are kept blind to the study groups. Blinding will be done using a placebo in the control group.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Baqiyatallah University of Medical Sciences
Street address
Baqiyatallah University of Medical Sciences, Shahid Nosrati Alley, Shaikh Bahai St., Vanak Square, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1435916471
Approval date
2020-03-29, 1399/01/10
Ethics committee reference number
IR.BMSU.REC.1399.156

Health conditions studied

1

Description of health condition studied
COVID-19
ICD-10 code
U07.2
ICD-10 code description
U07.2 COVID-19, virus not identified, COVID-19

Primary outcomes

1

Description
Measurement of cough severity
Timepoint
Day 1 before and at the end of treatment
Method of measurement
Standard cough questionnaire

2

Description
severity of shortness of breath
Timepoint
Day 1 before and at the end of treatment
Method of measurement
Shortness Of Breath With Daily Activity (SOBDA) Questionnaire

3

Description
lung radiologic changes
Timepoint
At beginning and end of the study
Method of measurement
Chest CT scan

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The product includes herbal syrup (Echinacea, thyme, hyssop, Chebulic Myrobaan), honey and glycyrrhizin drop.Dosage of syrup: every 6 hours;10 cc. Dosage of drop: 20 drops after lunch and dinner. In the intervention group, conventional medicine is used according to the latest protocol of the Ministry of Health at the begining of the study (Azithromycin 250mg once a day and naproxen 250mg twice a day).
Category
Treatment - Drugs

2

Description
Control group: In this group, the common drug is used according to the latest protocol of the Ministry of Health at the begining of the study that is similar to the common drug medicine in the herbal product group.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Baqiyatallah Hospital
Full name of responsible person
AHMAD REZA SHARIFI OLOUNABADI
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Mulla Sadra Street, Vanak Square, After Sheikh Baha'i, Baqiyatallah Hospital
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Dina Pharmed Exir Salamat Co
Full name of responsible person
Reza Hasanzade
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Kamal Shahr, next to Baharestan Industrial town, Medicinal Plants Science and Technology Park, postal code 1314744513
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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
Dina Pharmed Exir Salamat Co
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Other

Person responsible for general inquiries

Contact
Name of organization / entity
Dina Pharmed Exir Salamat Co
Full name of responsible person
Reza Hasanzade
Position
Research and Development Manager
Latest degree
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Other areas of specialty/work
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Assistant Professor

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Traditional Medicine

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Other areas of specialty/work
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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