

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Sep 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

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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 beginning 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 beginning 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

Street address

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

Street address

Kamal Shahr, next to Baharestan Industrial town, Medicinal Plants Science and Technology Park, postal code 1314744513

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Province

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Phone

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Email

reza.hasanzade7@gmail.com

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

Ph.D.

Other areas of specialty/work

Organic Chemistry

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Ahmad Reza Sharifi Olounabadi

Position

Assistant Professor

Latest degree

Ph.D.

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

Person responsible for updating data

Contact

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Ahmad Reza Sharifi Olounabadi

Position

Assistant Professor

Latest degree