

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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)

##### Phone

+98 21 8804 0060

##### Email address

a-sharifi@shahed.ac.ir

##### 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

##### City

Tehran

##### Province

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##### Postal code

1435915371

##### Phone

+98 21 8805 0436

##### Email

a-sharifi@shahed.ac.ir

## 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

#### City

Kamalshahr

#### Province

Alborz

#### Postal code

1314744513

#### Phone

+98 912 332 2848

#### 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

##### Street address

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

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+98 912 332 2848

##### Email

reza.hasanzade7@gmail.com

## 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**

Traditional Medicine

**Street address**

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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**