

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Sep 2026

Evaluation efficacy of a herbal combination (contains Glycyrrhiza glabra, Mentha pulegium and Urtica) in controlling symptoms in patients with COVID-19

Protocol summary

Study aim

Evaluation efficacy of a herbal combination (contains Glycyrrhiza glabra, Mentha pulegium and Urtica) in controlling symptoms in patients with COVID-19

Design

This study is a single-center, prospective, randomized, open-labeled, controlled, parallel phase 3 clinical trial.

Settings and conduct

Patients who is admitted to Baqiyatallah hospital, and is meet the inclusion criteria, is entered to the study are randomly assigned into two groups of intervention and control.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age equal or more than 18 years; The patient have written consciously and freely consent to participate in the study. The patient's clinical symptoms (dry cough, shortness of breath, fever) confirm COVID-19. Confirmed diagnosis of COVID-19, with either lung CT-Scan result, which is typical for COVID-19 pulmonary involvement, or RT-PCR confirmation. Less than 7 days have passed since the onset of symptoms
Exclusion criteria: history of allergy to ingredients; hypersensitivity reaction while taking this herbal nasal spray; The patient is in another clinical trial at the same time; The patient needs to receive medical care from the intensive care unit.

Intervention groups

Intervention group: Herbal nasal spray 1 puff every 8 hours, for 7 days (In addition to routine treatment according to the latest national guideline for the treatment of new corona-virus). Control group: routine treatment according to the latest national guideline for the treatment of new corona-virus.

Main outcome variables

Clinical symptoms changes (dry cough, respiratory distress, fever)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20080901001165N49**

Registration date: **2020-04-25, 1399/02/06**

Registration timing: **registered_while_recruiting**

Last update: **2020-04-25, 1399/02/06**

Update count: **0**

Registration date

2020-04-25, 1399/02/06

Registrant information

Name

Yunes Panahi

Name of organization / entity

Baqiyatallah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8821 1524

Email address

yunespanahi@bmsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-03-30, 1399/01/11

Expected recruitment end date

2020-05-31, 1399/03/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	
Scientific title	Evaluation efficacy of a herbal combination (contains Glycyrrhiza glabra, Mentha pulegium and Urtica) in controlling symptoms in patients with COVID-19
Public title	Evaluation efficacy of a herbal combination (contains Glycyrrhiza glabra, Mentha pulegium and Urtica) in controlling symptoms in patients with COVID-19
Purpose	Treatment
Inclusion/Exclusion criteria	
Inclusion criteria:	Age: equal or more than 18 years; The patient have written consciously and freely consent to participate in the study. The patient's clinical symptoms (dry cough, shortness of breath, fever) confirm COVID-19. Confirmed diagnosis of COVID-19, with either lung CT-Scan result, which is typical for COVID-19 pulmonary involvement, or RT-PCR confirmation. Less than 7 days have passed since the onset of symptoms.
Exclusion criteria:	History of allergy to this herbal nasal spray ingredients; Hypersensitivity reaction while taking this herbal nasal spray; The patient is in another clinical trial at the same time; The patient needs to receive medical care from the intensive care unit; Patient with uncontrolled hypertension; Hypokalemia (Potassium level<3.5 mmol/l); Pregnancy; Lactation.
Age	From 18 years old
Gender	Both
Phase	N/A
Groups that have been masked	No information
Sample size	Target sample size: 80
Randomization (investigator's opinion)	Randomized
Randomization description	Block-Randomization method is used to randomized the patients.
Blinding (investigator's opinion)	Not blinded
Blinding description	
Placebo	Not 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 Science
Street address	Baqiyatallah University of Medical Science, south Sheikh-Bahaei St., Mollasadra St., Vanak Sq., Tehran, Iran
City	Tehran
Province	Tehran
Postal code	1435916471
Approval date	2020-03-29, 1399/01/10
Ethics committee reference number	IR.BMSU.REC.1399.054
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	Clinical symptoms (dry cough)
Timepoint	Daily monitoring, but the result of baseline (before the initiation of intervention), and day 7 from the initiation, is recorded.
Method of measurement	Physical examination, questionnaire
2	
Description	Clinical symptoms (respiratory distress)
Timepoint	Daily monitoring, but the result of baseline (before the initiation of intervention), and day 7 from the initiation, is recorded.
Method of measurement	Pulse-oxymetry device
3	
Description	Clinical symptoms (fever)
Timepoint	Daily monitoring, but the result of baseline (before the initiation of intervention), and day 7 from the initiation, is

recorded.
Method of measurement
Thermometer

Secondary outcomes

1

Description

Lab. tests changes

Timepoint

Daily monitoring, but the before the intervention initiation (baseline) and day 7 results will recorded on designed checklist.

Method of measurement

Blood sample, laboratory analysis

Intervention groups

1

Description

Intervention group: Herbal nasal spray 1 puff every 8 hours, for 7 days (In addition to routine treatment according to the latest national guideline for the treatment of new corona-virus)

Category

Treatment - Drugs

2

Description

Control group: Routine treatment according to the latest national guideline for the treatment of new corona-virus.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Baqiyatallah hospital

Full name of responsible person

Ali Ghazivini

Street address

Baqiyatallah hospital, Mollasadra St., Vanak Sq., Tehran, Iran.

City

Tehran

Province

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Email

ghazvinia@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Andisheh Salamat Sabalan Medicinal Plants Company

Full name of responsible person

Siamak Mohammadi

Street address

Prohil Plant Products Complex, Shahid Dastgheib St., Shohada HWY, Ardebil, Iran.

City

Ardebil

Province

Ardabil

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5613786179

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Email

Savalanm452@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Baqiyatallah University of Medical Science

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

2

Sponsor

Name of organization / entity

Sina Darou Laboratories Company

Full name of responsible person

Dr. Rezaeiyan

Street address

Sina Darou Laboratories Company, Shahid Gornam St., 52th Boulevard, 15th km of Karaj special road

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Tehran

Province

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info@sinadarou.com

Grant name

Grant code / Reference number
Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Baqiyatallah University of Medical Science

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

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Hossein Biganeh

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Medical Pharmacy

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Baqiyatallah University of Medical Science, south
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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

Yunes Panahi

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Critical Care Pharmacotherapy

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Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Parisa Kianpour

Position

Assistant

Latest degree

Specialist

Other areas of specialty/work

Pharmacotherapy

Street address

Pharmacy faculty, Tehran University of Medical
Science, 16-Azar St., Enghelab Sq., Tehran, Iran.

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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