

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Investigating the efficacy of Zofa (a herbal medicine) in symptom management of patients with COVID-19

Protocol summary

Study aim

Investigating the effects of Zofa (a herbal composition) on the clinical symptoms Investigating the effects of Zofa (a herbal composition) on the laboratory findings

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. Confirmed diagnosis of COVID-19, with Laboratory (RT-PCR) confirmation. Confirmed diagnosis of COVID-19, with lung CT-Scan result, which is typical for COVID-19 pulmonary involvement. The patient has clinical symptom of COVID-19 (dry cough, respiratory distress, fever) Less than 7 days have passed since the onset of symptoms; Exclusion Criteria: The patient needs to receive medical care from the intensive care unit. The patient is in another clinical trial at the same time.

Intervention groups

intervention group: Syrup Zofa 10 ml every 8 hours for 7 days, in addition to routine treatment according to the latest national guideline for the treatment of new coronavirus Control group: routine treatment according to the latest national guideline for the treatment of new coronavirus

Main outcome variables

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

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20080901001165N48**
Registration date: **2020-04-22, 1399/02/03**
Registration timing: **registered_while_recruiting**

Last update: **2020-04-22, 1399/02/03**

Update count: **0**

Registration date

2020-04-22, 1399/02/03

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

2020-07-01, 1399/04/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the efficacy of Zofa (a herbal medicine) in symptom management of patients with COVID-19

Public title

Investigating the efficacy of Zofa (a herbal medicine) in symptom management of 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. Confirmed diagnosis of COVID-19, with Laboratory (RT-PCR) confirmation. Confirmed diagnosis of COVID-19, with lung CT-Scan result, which is typical for COVID-19 pulmonary involvement. The patient has clinical symptom of COVID-19 (dry cough, respiratory distress, fever) Less than 7 days have passed since the onset of symptoms;

Exclusion criteria:

The patient is in another clinical trial at the same time. The patient needs to receive medical care from the intensive care unit

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **100**

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 hospital, 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.1399.027

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: Syrup Zofa 10 ml 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 Ghazvini

Street address

Baqiyatallah hospital, Mollasadra st., Vanak sq., Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1435916471

Phone

+98 21 8245 5393

Email

ghazvinia@gmail.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Niak pharmaceutical company

Full name of responsible person

Hooman Bayat

Street address

Pasdaran St., Berlian Passage, 3rd floor

City

Gorgan

Province

Golestan

Postal code

49175/596

Phone

+98 17 3222 9229

Email

Niak.pharmaceutical@gmail.com

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

Yes

Title of funding source

Niak pharmaceutical company

Proportion provided by this source

50

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**

Industry

2**Sponsor****Name of organization / entity**

Vice Chancellor for Research, Baqiyatallah University of Medical Sciences

Full name of responsible person

Gholam Hosein Alishiri

Street address

Baqiyatallah university of medical science, south Sheikh-Bahaei St., Mollasadra St., Vanak Sq., Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1435916471

Phone

+98 21 8245 5393

Email

R.bmsu@yahoo.com

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

Yes

Title of funding source

Vice Chancellor for Research, Baqiyatallah University of Medical Sciences

Proportion provided by this source

50

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

Ali Ghazvini

Position

Assistant of Professor

Latest degree

Subspecialist

Other areas of specialty/work

respiratory disease

Street address

Baqiyatallah university of medical science, south
Sheikh-Bahaei St., Mollasadra St., Vanak Sq., Tehran,
Iran

City

Tehran

Province

Tehran

Postal code

1435916471

Phone

+98 21 8245 5393

Email

qazvinia@gmail.com

Postal code

1435916471

Phone

+98 21 8245 5393

Email

Yunespanahi@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Parisa Kianpour

Position

Pharmacotherapy 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

City

Tehran

Province

Tehran

Postal code

1417614411

Phone

+98 21 6695 4709

Email

parisa_kianpour@yahoo.com

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 fellowship

Street address

Baqiyatallah university of medical science, south
Sheikh-Bahaei St., Mollasadra St., Vanak Sq., Tehran,
Iran

City

Tehran

Province

Tehran

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