Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 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: **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
Baqiyattalah 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 oxymetery 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

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1435916471

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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

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49175/596

Phone

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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

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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

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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 Pharmacotherpy fellowship

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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

Pharmacotherapy assistant

Latest degree

Specialist

Other areas of specialty/work

Pharmcotherapy

Street address

Pharmacy faculty, Tehran University of medical science, 16-Azar St., Enghelab Sq., Tehran, Iran

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Province

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parisa_kianpour@yahoo.com

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