Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Oct 2020

Effect evaluation of herbal supplementation from the combination of sugarcane, black myrobalan and mastic along with the treatment protocol of the Ministry of Health on the course of COVID-19 disease

Protocol summary

Study aim
Reduce the duration of treatment Disease severity phase prevention

Design
Clinical trial with control group, with parallel intervention, double-blind, randomized

Settings and conduct
In Peymaniyeh Hospital of Jahrom, in two groups of intervention and control as follows: Intervention group: Receiver of herbal supplements from a combination of 1000 mg of black myrobalan and 2000 mg of mastic and 3000 mg of sugarcane along with the treatment protocol approved by the Ministry of Health. Control group: Receiver of treatment protocol approved by the Ministry of Health and placebo. The distribution of herbal supplements in the intervention group and placebo in the control group will be done by nurses based on the randomization result announced by the head nurse. The researcher and nurses will not know the randomization results and the type of package that are being given to the patient. The researcher should only provide the necessary supplement for the intervention and provide it to the head nurse.

Participants/Inclusion and exclusion criteria
Study participation criteria: • All patients admitted with a diagnosis of COVID-19 • COVID-19 patients who are willing to participate in study • The patient should not be among high-risk groups, such as breastfeeding or pregnant or etc. • Age> 18 years old • The patient does not have a specific underlying disease. Study exclusion criteria: • Dissatisfaction with continuing with herbal supplements treatment • herbal supplements Intolerance (in case of allergies and other similar cases) • After admission to the ICU • Positive pregnancy test

Intervention groups
Herbal supplement taking group (5 people). Placebo taking group (5 people)

Main outcome variables
Chest CT scan findings; Erythrocyte sedimentation rate; C-Reactive Protein; Clinical signs

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200415047082N1**
Registration date: **2020-04-21, 1399/02/02**
Registration timing: **prospective**

Last update: **2020-04-21, 1399/02/02**
Update count: **0**

Registration date
2020-04-21, 1399/02/02

Registrant information

Name
esmail rayat dost

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 71 5427 7145

Email address
e.rayatdost@jums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-05-04, 1399/02/15

Expected recruitment end date
2020-06-04, 1399/03/15

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect evaluation of herbal supplementation from the combination of sugarcane, black myrobalan and mastic along with the treatment protocol of the Ministry of Health on the course of COVID-19 disease

Public title
Effect evaluation of herbal supplementation from the combination of sugarcane, black myrobalan and mastic along with the treatment protocol of the Ministry of Health on the course of coronavirus disease
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
All patients admitted with a diagnosis of COVID-19 COVID-19 patients who are willing to participate in study The patient should not be among high-risk groups, such as breastfeeding or pregnant or etc. Age> 18 years old The patient does not have a specific underlying disease Study
Exclusion criteria:
People who are under 18 years of age People who are among the high-risk group People who have a specific underlying disease People who are characterized as severe in the illness course
Age
From **18 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **10**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization method: Simple randomization Randomization unit: individual Randomization tool: from random number table by assigning a code to each patient by the head nurse Allocation concealment: The distribution of herbal supplements in the intervention group and placebo in the control group will be done by nurses based on the randomization result announced by the head nurse. The researcher and nurses will not know the randomization results and the type of package that are being given to the patient. The researcher should only provide the necessary supplement for the intervention and provide it to the head nurse.
Blinding (investigator's opinion)
Double blinded
Blinding description
The distribution of herbal supplements in the intervention group and placebo in the control group will be done by nurses based on the randomization result announced by the head nurse. The researcher and nurses will not know the randomization results and the type of package that are being given to the patient. The researcher should only provide the necessary supplement for the intervention and provide it to the head nurse.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Jahrom University of Medical Sciences
Street address
Jahrom University of Medical Sciences, Shahid Motahari Ave.
City
Jahrom
Province
Fars
Postal code
7414846199
Approval date
2020-04-14, 1399/01/26
Ethics committee reference number
IR.JUMS.REC.1399.003

Health conditions studied

1

Description of health condition studied
New Corona virus disease 2019
ICD-10 code
U07.1
ICD-10 code description
new Corona virus disease 2019

Primary outcomes

1

Description
Symptoms of disease
Timepoint
During the hospital stay, on a daily basis
Method of measurement
The severity of patient's clinical symptoms is measured

on the basis of visual analog scale.

2

Description
Vital Signs
Timepoint
During the hospital stay, on a daily basis
Method of measurement
Vital signs monitoring device

3

Description
C-Reactive Protein
Timepoint
During the hospital stay, on a daily basis
Method of measurement
C-Reactive Protein test

Secondary outcomes

1

Description
Pulmonary damages after illness
Timepoint
At the beginning of the study and 14 and 30 days after taking herbal supplements
Method of measurement
Chest Computed Tomography Scan

Intervention groups

1

Description
Intervention group: herbal supplement taking from a combination of 1000 mg of black myrobalan and 2000 mg of mastic and 3000 mg of sugarcane twice a day without water. The duration of herbal supplement taking is one week.
Category
Treatment - Drugs

2

Description
Control group: Placebo taking twice a day Without water. The duration of placebo taking is one week.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Peymanieh hospital
Full name of responsible person
Rahim raufi
Street address
Vali-e-Asr Ave., Peymaniyeh Hospital
City
Jahrom
Province
Fars
Postal code
7414846199
Phone
+98 71 5423 0010
Email
sarahim1513@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Jahrom University of Medical Sciences
Full name of responsible person
Kavous solhjou
Street address
Jahrom University of Medical Sciences, Shahid Motahari Ave.
City
Jahrom
Province
Fars
Postal code
7414846199
Phone
+98 71 5434 0405
Email
solhjouk@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Jahrom University of Medical Sciences
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
Jahrom University of Medical Sciences
Full name of responsible person
Alireza hashemi shiri
Position

Extern

Latest degree
A Level or less

Other areas of specialty/work
General Practitioner

Street address
Shahid Motahari Ave., University of Medical Sciences, Research Unit

City
Jahrom

Province
Fars

Postal code
7414846199

Phone
+98 902 001 0987

Email
Entezar14arh@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Jahrom University of Medical Sciences

Full name of responsible person
Esmail Rayat dost

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Emergency Medicine

Street address
Vali-e-Asr Ave., Peymaniyeh Hospital

City
Jahrom

Province
Fars

Postal code
7414846199

Phone
+98 71 5427 7145

Email
e.rayat.dost@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Jahrom University of Medical Sciences

Full name of responsible person
Alireza hashemi shiri

Position
Extern

Latest degree
A Level or less

Other areas of specialty/work
General Practitioner

Street address
Shahid Motahari Ave., University of Medical Sciences, Research Unit

City
Jahrom

Province
Fars

Postal code
7414846199

Phone
+98 902 001 0987

Fax

Email
Entezar14arh@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Not applicable

Title and more details about the data/document
All potential data will be shared after people get unrecognizable

When the data will become available and for how long
Start of access period from 1399

To whom data/document is available
For public

Under which criteria data/document could be used
Free access

From where data/document is obtainable
for public

What processes are involved for a request to access data/document
by requesting from corresponding writer

Comments