

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Jahrom University of Medical Sciences

Full name of responsible person

Kavous solhjou

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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
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Person responsible for updating data

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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