

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Efficacy evaluation of an herbal compound “Fluherb” on clinical symptoms and paraclinical parameters in highly suspected COVID-19 patients: a controlled randomized clinical trial.

Protocol summary

Study aim

Evaluation of the effect of a herbal compound on patients with clinical and CT scan findings strongly suspected of COVID-19

Design

This study is a randomized controlled clinical trial in which patients will be simply selected from hospitalized patients with corona. Individuals with eligibility criteria will be randomly divided into two groups of intervention and control, and 30 patients will be enrolled in each group. The study is three-blinded and the patient, the nurse giving the medication, the data collector, and the data analyzer are not aware of the type of assignment.

Settings and conduct

This study will be carried out at Imam Reza Hospital, one of the hospitals affiliated to Mashhad University of Medical Sciences. This hospital has been assigned for corona patients. This research will be carried out in March and April of 2020.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Hospitalized patients who are suspected to COVID-19 based on clinical symptoms and computed tomography findings; Clinically classified as moderate and severe; No organ damage; age under 70 years; They are stable in cardiovascular status. Non-inclusion criteria: Pregnant and lactating women; End stage patients

Intervention groups

This study consists of two groups. Intervention group will receive a herbal compound so-called Fluherb containing extracts of purslane, Plantain, hyssop, licorice and turmeric prepared in suspension dosage form. The control group received a placebo syrup. The intervention period is five days and the drug will be administered orally in three divided doses. Both groups receive all current treatments and will be matched according to clinical status.

Main outcome variables

Changes in clinical conditions and severity of disease

General information

Reason for update

The expiration date of the study was changed due to problems in patient selection and hospital ward restrictions. The elderberry fruit available in the market is not of good quality and in the initial evaluation it seemed that the cyanide level is higher than the standard, so the leaves of the hyssop were replaced and instead of hydroethanolic extract, a more safe aqueous extract was used. In addition, due to the low quality of the plantain leaves in the market, plantain seed were used instead of its leaves.

Acronym

IRCT registration information

IRCT registration number: **IRCT20200323046841N1**
Registration date: **2020-03-28, 1399/01/09**
Registration timing: **registered_while_recruiting**

Last update: **2020-04-11, 1399/01/23**

Update count: **1**

Registration date

2020-03-28, 1399/01/09

Registrant information

Name

Mahdi Yousefi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3876 6148

Email address

yousefim@mums.ac.ir

Recruitment status

Recruitment complete**Funding source****Expected recruitment start date**

2020-03-28, 1399/01/09

Expected recruitment end date

2020-05-09, 1399/02/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy evaluation of an herbal compound "Fluherb" on clinical symptoms and paraclinical parameters in highly suspected COVID-19 patients: a controlled randomized clinical trial.

Public title

Efficacy evaluation of an herbal compound in COVID-19

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Hospitalized patients with clinical and CT scan findings strongly suspected of COVID -19 Relative stability in cardiovascular status Moderate and severe cases No organ damage

Exclusion criteria:

Pregnant and lactating women End stage patients

AgeTo **70 years** old**Gender**

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample sizeTarget sample size: **60****Randomization (investigator's opinion)**

Randomized

Randomization description

Balanced block randomization

Blinding (investigator's opinion)

Triple blinded

Blinding description

In this study, patients will be informed by consent form that they would either be in the intervention group or the control group, but they won't be aware of the type of medication. Nurses who supply the drug are also unaware of its content because the appearance, taste, color, and prescription of the drug are similar, but the code on the drug will be different. The written codes on the drugs are random and only the pharmacist's partner is aware of the drug type and the inserted code on it.

The patient data collector and the project statistical partner are also unaware of the type of intervention. As the control group uses placebo, which is similar in appearance, taste, color, and prescription, patients will be unaware of the type of drug being administered.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Mashhad University of Medical Sciences

Street address

School of Persian and Complementary Medicine; University Campus; Azadi Square

City

Mashhad

Province

Razavi Khorasan

Postal code

9177745346

Approval date

2020-03-14, 1398/12/24

Ethics committee reference number

IR.MUMS.REC.1398.315

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**

Changing the patient's clinical status in the COVID-19 clinical classification table

Timepoint

Before and after intervention

Method of measurement

Clinical and Paraclinical Indicators in COVID-19 Classification Table

Secondary outcomes

1

Description

Cell blood count

Timepoint

Before and after the intervention

Method of measurement

Cell counter

2

Description

Liver enzymes

Timepoint

Before and after the intervention

Method of measurement

spectrometer

Intervention groups

1

Description

Intervention group: This group will receive routine treatments for COVID-19 disease and will receive a suspension of extract of five herbs. Patients will receive a combination consisted of aqueous extract of 10 grams of hyssop leaf, 5 grams of Plantain seed, 10 grams of purslane seed, 10 grams of licorice root and 5 grams of turmeric, orally, in three divided doses daily. The intervention duration is five days.

Category

Treatment - Drugs

2

Description

Control group: This group receive routine treatments for COVID-19 disease and placebo. Placebo will be given as an oral syrup, three servings a day. For the placebo syrup, a non-absorbable sweetened drop of stevia (a product from a pharmaceutical company), authorized oral dyes are used to make the color and taste relatively similar to the original drug.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza hospital

Full name of responsible person

Mahdi Yousefi

Street address

Imam Reza square

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Mohsen Tafaghodi

Street address

Daneshgah avenue

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Mashhad

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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

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Mahdi Yousefi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

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Associate professor

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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