Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 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 hydroethonolic 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)

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+98 51 3876 6148

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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

Age
To **70 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target 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 conuter

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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9138813944
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RIS@mums.ac.ir
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

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Person responsible for updating data

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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