

# 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

**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

##### City

Mashhad

#### Province

Razavi Khorasan

#### Postal code

9177745346

#### Phone

+98 51 3854 3031

#### Email

yousefim@mums.ac.ir

## 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

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

9138813944

##### Phone

+98 51 3841 2081

##### Email

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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**Province**

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0091 51 38848930

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

Mashhad University of Medical Sciences

**Full name of responsible person**

Mahdi Yousefi

**Position**

Associate professor

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Mashhad University of Medical Sciences

**Full name of responsible person**

Mahdi Yousefi

**Position**

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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