# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

05 Sep 2026

## Evaluation of the effect of IMFLUNA herbal compound on the improvement of covid-19 pneumonia symptoms in patients referred to Baqiyatallah Hospital

## Protocol summary


**Study aim**

To investigate the effects of herbal compound IMFLUNA on improving the symptoms of patients with covid-19 pneumonia

**Design**

This double-blind, phase 2 clinical trial is performed in 60 patients with covid-19 pneumonia. Patients are randomly assigned to 30 blocks of 2 patients. Each patient in the block then receives herbal or placebo capsule with code A or B. So that 30 patients are given herbal compound and 30 people are given placebo.The duration of treatment is two weeks.

**Settings and conduct**

Sixty eligible patients with covid-19 pneumonia referred to Baqiyatallah Hospital will be selected and randomly divided into two groups of 30 each. The patients are given by nurse any of herbal or placebo capsule package for two weeks medication with an identification code of A or B. The package identification code are recorded in the patient's medical records. The physician, nurse, patients, data collector and who evaluate the outcome are unaware of the herbal and placebo group. Only the expert in charge of packaging knows the type of groups. Patients are unaware of the type of group they are in.

**Participants/Inclusion and exclusion criteria**

Inclusion criteria: patients with covid-19 pneumonia, aged 20 to 70 years who have the ability to take oral medication. Exclusion criteria: patients with severe dyspnea require mechanical ventilation or hospitalization in intensive care units, and patients with treatment-resistant hypoxemia or those with severe underlying disease and pregnant women

**Intervention groups**

Intervention group: patients in this group receive two 500 mg capsules of herbal compound three times a day after post meal. Placebo group: patients in this group receive two 500 mg capsules of placebo three times a day after post meal.

**Main outcome variables**

Main outcome variables are blood oxygen saturation, respiratory rate and lung inflammation.


## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20080901001157N16**
Registration date: **2020-04-08, 1399/01/20**
Registration timing: **registered_while_recruiting**

Last update: **2020-04-08, 1399/01/20**
Update count: **0**

**Registration date**

2020-04-08, 1399/01/20

**Registrant information**


**Name**

Hasan Fallah Huseini

**Name of organization / entity**

Institute of Medicinal Plants

**Country**

Iran (Islamic Republic of)

**Phone**

+98 26 3476 4010

**Email address**

fallah@imp.ac.ir


**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2020-03-30, 1399/01/11

**Expected recruitment end date**

2020-05-31, 1399/03/11

**Actual recruitment start date**
empty
**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
Evaluation of the effect of IMFLUNA herbal compound on the improvement of covid-19 pneumonia symptoms in patients referred to Baqiyatallah Hospital

**Public title**
Effect of IMFLUNA herbal compound on covid-19 pneumonia symptoms
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Patients infected with symptomatic covid-19 pneumonia virus Confirmation of coronavirus infection with chest CT scan and PCR test Age 20 to 70 years who have the ability to take oral medication Personal desire to participate in the project and the signing of a written consent
**Exclusion criteria:**
Patients with severe dyspnea Patients with reduced level of consciousness or need hospitalization in intensive care units Patients with swallowing disorders or possibility of aspiration of food or unable to take the drug orally Patients with respiratory failure require mechanical ventilation Patients with resistant hypoxemia Patients with organ transplantation; malignant disease; treated with corticosteroids or chemotherapy Patients with uncontrolled blood pressure, uncontrolled diabetes, cardiovascular disease and underlying respiratory disease Pregnant women
**Age**
From **20 years** old to **70 years** old
**Gender**
Both

**Phase**
1-2
**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

**Sample size**
Target sample size: **60**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
A random number table and block randomization method is used. In this method 60 eligible patients are assigned into 30 blocks of 2 patients. Then, each of the 2 patients in the block is randomly assigned to take herbal medicine or placebo, so that 30 patients assigned to each group.
**Blinding (investigator's opinion)**
Triple blinded
**Blinding description**
Package for herbal and placebo is labeled with code B or A. Other specifications on the labels are identical. Physicians, nurses, patients, data collectors and those who evaluate the outcome are unaware of the drug and placebo group. Only the expert who has done the capsules packaging is aware of the contents of the packages or what is code A or B. Patients are aware that they are either in the herbal drug or placebo groups, but they are not aware of the type of group they are in
**Placebo**
Used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Baqiyatallah University of Medical Sciences
**Street address**
Baqiyatallah University of Medical Sciences, Vanak square, Molasadra Ave
**City**
Tehran
**Province**
Tehran
**Postal code**
1484958693
**Approval date**
2020-03-29, 1399/01/10
**Ethics committee reference number**
IR.BMSU.REC.1399.036

## Health conditions studied

### 1

**Description of health condition studied**
COVID-19 pneumonia
**ICD-10 code**
RA01.0
**ICD-10 code description**
Confirmed diagnosis of COVID-19

## Primary outcomes

### 1

**Description**
Blood oxygen saturation
**Timepoint**
At beginning and regularly during study

**Method of measurement**
Pulse Oximeter

**2**

**Description**
Respiratory Rate
**Timepoint**
At beginning and regularly during study
**Method of measurement**
Respiratory Count

**3**

**Description**
lung inflammation
**Timepoint**
At beginning and end of the study
**Method of measurement**
Chest CT scan

## Secondary outcomes

**1**

**Description**
C-reactive protein
**Timepoint**
At beginning and end of the study
**Method of measurement**
Intravenous blood test

**2**

**Description**
CBC
**Timepoint**
At beginning and end of the study
**Method of measurement**
Intravenous blood test

**3**

**Description**
ESR
**Timepoint**
At beginning and end of the study
**Method of measurement**
Intravenous blood test

**4**

**Description**
BUN
**Timepoint**
At beginning and end of the study
**Method of measurement**
Intravenous blood test

**5**

**Description**
Creatinine
**Timepoint**
At beginning and end of the study
**Method of measurement**
Intravenous blood test

**6**

**Description**
K
**Timepoint**
At beginning and end of the study
**Method of measurement**
Intravenous blood test

**7**

**Description**
Na
**Timepoint**
At beginning and end of the study
**Method of measurement**
Intravenous blood test

**8**

**Description**
Cough
**Timepoint**
At beginning and regularly during the study
**Method of measurement**
Count

**9**

**Description**
Fever
**Timepoint**
At beginning and regularly during the study
**Method of measurement**
Termometer

**10**

**Description**
ALT
**Timepoint**
At beginning and end of the study
**Method of measurement**
Intravenous blood test

**11**

**Description**
AST
**Timepoint**
At beginning and end of the study
**Method of measurement**
Intravenous blood test

**12**

**Description**
ALK
**Timepoint**

At beginning and end of the study

**Method of measurement**

Intravenous blood test

## Intervention groups

### 1

**Description**

Intervention group: patients in this group in addition to receiving standard medications, take two 500 mg capsules of the herbal compound three times a day after meals. The herbal capsule contains a mixture of medicinal plant extract powder and is manufactured by the HomaPharmed Pharmaceutical Company. The herbal capsule is given as a supplement to patients for two weeks along with standard medications.

**Category**

Treatment - Drugs

### 2

**Description**

Control group: patients in this group in addition to receiving standard medications, take two 500 mg capsules of the placebo three times a day after meals. The placebo capsule contains a toasted powder is manufactured by the HomaPharmed Pharmaceutical Company. The placebo capsule is given as a supplement to patients for two weeks along with standard medications.

**Category**

Placebo

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**

Baqiyatallah University of Medical Sciences

**Full name of responsible person**

Reza Mohtashami

**Street address**

Vanak square, Molasadra Ave

**City**

Tehran

**Province**

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**Postal code**

1484958693

**Phone**

+98 21 8806 8923

**Email**

rmohtashami@yahoo.com

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

HomaPharmed Company

**Full name of responsible person**

Morteza Khairabadi

**Street address**

Enghelab Square, North Jamalzadeh St., Nader Alley., No 26

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**Postal code**

1418635643

**Phone**

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**Fax**

+98 21 6690 8071

**Email**

info@homapharmed.com

**Web page address**

http://www.homapharmed.com

**Grant name**

Agreement

**Grant code / Reference number**

17/1/1399- 5/340/س

**Is the source of funding the same sponsor organization/entity?**

No

**Title of funding source**

HomaPharmed Company

**Proportion provided by this source**

100

**Public or private sector**

Private

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

Industry

## Person responsible for general inquiries

**Contact**

**Name of organization / entity**

Institute of Medicinal Plants

**Full name of responsible person**

Fallah Huseini Hasan

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Medical Pharmacy

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## Person responsible for scientific inquiries

**Contact**
**Name of organization / entity**
HomaPharmed Company
**Full name of responsible person**
Mohammadreza Gholibeikian
**Position**
Director of R and D
**Latest degree**
Ph.D.
**Other areas of specialty/work**
Medical Pharmacy
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## Person responsible for updating data

**Contact**
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**Full name of responsible person**
Mohammadreza Gholibeikian
**Position**
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**Other areas of specialty/work**
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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