

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 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

Tehran

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

City

Tehran

Province

Tehran

Postal code

1418635643

Phone

+98 21 6276 9000

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

Street address

Kavosh Blvd., Supa Blvd., Poleh Kordan

City

karaj

Province

Alborz

Postal code

3365166571

Phone

+98 26 3476 4010

Email

h.fallah@acecr.ac.ir

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

Street address

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

City

Tehran

Province

Tehran

Postal code

1418635643

Phone

+98 21 6276 9000

Fax

+98 21 6690 8071

Email

mgholibeikian@gmail.com

Person responsible for updating data**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

Street address

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

City

Tehran

Province

Tehran

Postal code

1418635643

Phone

+98 21 6276 9000

Email

mgholibeikian@gmail.com

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