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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

HomaPharmed Company

Full name of responsible person

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

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Fax

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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
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Ph.D.
Other areas of specialty/work
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Person responsible for updating data

Contact
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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