

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Effectiveness of HMD 99 capsule (St. John's wort and Lemon Balm extract along with DDW water) in the treatment of patients with COVID-19 disease referred to Imam Khomeini Hospital in Tehran: a randomized double blind clinical trial study.

Protocol summary

Study aim

To study the effectiveness of the formulated capsule containing the extract of Hypericum p. and Melissa o., with deuterium depleted water, in patients with covid-19 who volunteer at the Imam Khomeini Hospital, Tehran

Design

Phase 3 clinical study, 110 patients, double blind and randomized according to a randomized chart, with two groups: control (placebo) and treatment (HMD 99 capsules)

Settings and conduct

After patient selection according to guidelines for this randomized double-blind experimental study, they will be divided into two groups (control and treatment) of 55 patients in each group. The experiment will be performed at the Imam Khomeini hospital for 14 days. The assessment of the effectiveness of the formulation will be determined by comparing the experimental results between the control and the treated groups

Participants/Inclusion and exclusion criteria

Patients must give oral and written consent to join study, must be 18 years or older, positive SARS-CoV-2 PCR test or one of the following: clinical signs indicative of Covid-19 including fever, dry cough, shortness of breath, CT scan (HRCT or Spiral Ct) showing coronavirus symptoms, specifically ground glass view in the peripheral or basal area of the lungs, patients who have ARDS or myocarditis. Patients should not have taken anti-retroviral medications or drugs to boost the immune system within 3 months of the commencement of the study.

Intervention groups

The control group shall receive 3 capsules of placebo, and the experimental group shall receive 3 HMD 99 formulation capsules per day for a period of 90 days

Main outcome variables

Blood Test CBC, (Diff-ESR-CRP-Ast-Alt-Cr-D Dimer),
Clinical manifestations: Respiratory symptoms or common acute and non-respiratory symptoms such as lethargy, fever, myalgia, dry cough, phlegm, diarrhea, shortness of breath, rhinitis, vomiting, headaches, chills

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210216050373N2**

Registration date: **2021-12-19, 1400/09/28**

Registration timing: **prospective**

Last update: **2021-12-19, 1400/09/28**

Update count: **0**

Registration date

2021-12-19, 1400/09/28

Registrant information

Name

Seyed ahmad Seyed alinaghi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

s_a_alinaghi@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-04, 1400/10/14

Expected recruitment end date

2022-01-20, 1400/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of HMD 99 capsule (St. John's wort and Lemon Balm extract along with DDW water) in the treatment of patients with COVID-19 disease referred to Imam Khomeini Hospital in Tehran: a randomized double blind clinical trial study.

Public title

Effectiveness of HMD 99 capsule (St. John's wort and Lemon Balm extract along with DDW water) in the treatment of patients with COVID-19 disease

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

To participate in the study, patients, or their legal guardian must give their knowing and voluntary consent in writing and orally The PCR test for SARS-CoV-2 virus must be positive with one of the following conditions: signs indicating covid-19 disease such as fever, dry cough and shortness of breath CT scan (HRCT or Spiral CT) to show coronavirus involvement, specifically in the ground glass view in the peripheral or basal portions of the lungs and physician's confirmation Patients who have signs of medical conditions secondary to covid-19 infection such as Acute Respiratory Distress Syndrome (ARDS) or myocarditis Patients should not have taken antiretroviral or boosters of immune system up to 3 months prior to the start of the study

Exclusion criteria:

Patients will not participate in this study during pregnancy or lactation Patients whose covid-19 infection has not been confirmed but have cold or flu-like symptoms. Current use of stimulants or depressant drugs or alcohol Use of growth hormone, testosterone or anabolic steroids up to 30 days prior to the start of the study Long-term treatment with immunosuppressant medications except topical steroids Patients undergoing chemotherapy, radiotherapy (up to 3 weeks prior to the start of the experiment) or patients who have been prescribed interferon

Age

From 18 years old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: 110

Randomization (investigator's opinion)

Randomized

Randomization description

A table of randomized numbers (with a number for each patient) shall be used for randomization of treatment in the study. In this table, half the numbers are coded for HMD 99 capsule and the other half for placebo without the administrators prior knowledge. Prescription of HMD 99 capsule or placebo for each patient shall be done by picking numbers from the table and matching them to the code for the medication or placebo.

Blinding (investigator's opinion)

Double blinded

Blinding description

This is double-blind study in which neither the patients nor the medical care staff/physicians will have information regarding treatment (capsule or placebo) each patient is receiving. The double-blind set up of the study will use coded packages for capsules and placebo which look identical

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research Ethics Committee Of Islamic Azad University, Tehran

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Shariati St., Khaghani St.

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Province

Tehran

Postal code

1916893813

Approval date

2021-12-15, 1400/09/24

Ethics committee reference number

IR.IAU.QOM.REC.1400.075

Health conditions studied**1****Description of health condition studied**

Covid-19

ICD-10 code

U07.1

ICD-10 code description

COVID 19, virus identified

Primary outcomes

1

Description

Blood test (CBC, Diff-ESR-CRP-Ast-Alt-Cr-D Dimer)

Timepoint

At the beginning, and after 14 days at the end of the study

Method of measurement

Blood Test CBC, (Diff-ESR-CRP-Ast-Alt-Cr-D Dimer)

Secondary outcomes

1

Description

Clinical manifestations: Respiratory symptoms or common acute and non-respiratory symptoms such as lethargy, fever, myalgia, dry cough, phlegm, diarrhea, shortness of breath, rhinitis, vomiting, headaches, chills

Timepoint

daily for 14 days

Method of measurement

Physician's examination, patients answers, information recorded in patient files

Intervention groups

1

Description

Intervention group: This group shall receive 3 HMD 99 capsules per day, each containing 400 mg of Hypericum p. and Melissa o. formulation prepared with deuterium depleted water, for 90 days.

Category

Treatment - Drugs

2

Description

Control group: This group shall receive and take 3 placebo capsules (containing commonly used excipients in pharmaceuticals for producing placebo) for 90 days

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Doctor Seyed Ahmad Alinaghi, Physician

Street address

End of Keshavarz Blvd., Dr. Gharib St.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Imam Khomeini Hospital, Tehran

Full name of responsible person

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Email

Imamhospital@tums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Imam Khomeini Hospital, Tehran

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

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Imam Khomeini Hospital, Tehran

Full name of responsible person

Seyed Ahmad Alinaghi, M.D.

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

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Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

PNU University

Full name of responsible person

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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