Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 HDM 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)

Phone

+98 21 6658 1583

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
Street address
Shariati St., Khaghani St.
City
Tehran
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.
City
Tehran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Imam Khomeini Hospital, Tehran
Full name of responsible person
Dr. Seyed Ahmad Alinaghi, M.D.
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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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Person responsible for updating data

Contact
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Bachelor
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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