Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 2026

Evaluation of the effectiveness of complementary therapy with Portulaca oleracea capsule on the clinical symptoms of outpatients with COVID-19

Protocol summary

Study aim
Evaluation of the effectiveness of Portulaca Oleracea extract on the clinical COVID-19

Design
Clinical trial with control group, with parallel groups, double-blind, randomized, block method, phase 3 on 140 patients. For randomization, the balanced block method is used using 4 blocks using SAS software.

Settings and conduct
Patients who have Covid 19 (RT-PCR confirmation) and have referred to the 16-hour treatment centers of Mashhad University of Medical Sciences and have the inclusion criteria, are included in the study. After obtaining informed consent, patients are randomly divided into 2 groups. The placebo group will receive the usual treatments and the placebo capsule and the intervention group, in addition to the usual treatments, will receive an oral capsule of portulaca oleracea extract at a dose of 600 mg (divided into a dose of 300 mg twice a day) for 2 weeks. Clinical and laboratory signs and symptoms will be studied, evaluated and compared before and after the intervention in both groups. The recovery time of symptoms including shortness of breath, anorexia, and oxygen saturation of the blood will be compared. The two groups are matched and equalized in terms of age, comorbidities, severity of Qovid involvement, and clinical symptoms.

Participants/Inclusion and exclusion criteria
Outpatients with PCR-approved Covid-19 with 90% oxygen have no underlying disease and are not pregnant or breastfeeding

Intervention groups
In the intervention group, 600 mg of Portulaca Oleracea extract is given to patients along with common drugs. Control group (placebo) receive only common drugs with placebo.

Main outcome variables
Improvement of clinical symptoms (fever, cough and myalgia) and paraclinical (time of normalization of lymphopenia and CRP)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190303042889N1**
Registration date: **2021-03-30, 1400/01/10**
Registration timing: **prospective**

Last update: **2021-03-30, 1400/01/10**
Update count: **0**

Registration date
2021-03-30, 1400/01/10

Registrant information

Name
Zahra Habibian

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 51 3221 4363

Email address
habibiannezhadz971@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-05-05, 1400/02/15

Expected recruitment end date
2021-09-21, 1400/06/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Evaluation of the effectiveness of complementary therapy with Portulaca oleracea capsule on the clinical symptoms of outpatients with COVID-19

Public title
Evaluation of the effectiveness of complementary therapy with Portulaca oleracea capsule on the clinical symptoms of outpatients with COVID-19

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Outpatient with COVID-19 Age 18-60 years Patient satisfaction Being alert and lacking organ damage Confirmation of RT-PCR test for SARS-CoV-2 Blood saturated oxygen content more than 90%

Exclusion criteria:
Pregnant and lactating women comorbidity End stage Patient

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description
In order to allocate individuals in the two groups of 70 people studied, the blocking method will be used and for this purpose, among the given probabilities, four blocks have been randomly selected, which include: 1- ABBA- 2- AABB- 3- BABA-4-BBAA and each patient visited in one of the first or second groups will be entered in the blocks mentioned above, respectively. After completing the four blocks, the allocation of individuals in the study groups starts again from block one to complete the 140 samples required in the study.

Blinding (investigator's opinion)
Double blinded

Blinding description
This study is a clinical trial with two groups of control and intervention in which placebo is used. For blinding the study, drug form would be similar in two groups and the allocation of individuals is based on the block randomization method. The prescribing physician and the patient will not know the type of capsule that was the medication or the placebo.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Mashhad University of Medical Sciences

Street address
Mashhad University of Medical Sciences, Azadi Square, Mashhad

City
Mashhad

Province
Razavi Khorasan

Postal code
9177948564

Approval date
2021-02-27, 1399/12/09

Ethics committee reference number
IR.MUMS.REC.1399.646

Health conditions studied

1

Description of health condition studied
COVID-19

ICD-10 code
U07.1

ICD-10 code description
COVID-19

Primary outcomes

1

Description
Improvement time of clinical manifestation based on questionnaire

Timepoint
The beginning of the intervention & day 14

Method of measurement
questionnaire

2

Description
Normalization of CRP and lymphopenia

Timepoint
The beginning of the intervention & day 14

Method of measurement
laboratory

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Receive common treatments and 300 mg of Portulaca Oleracea extract capsules 2 times a day for 7 days
Category
Treatment - Drugs

2

Description
Control group: Receive common treatments and placebo capsules
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
16-hour corona centers
Full name of responsible person
SeyedeZahra Habibiannezhad
Street address
Mashhad university of medical science, Azadi square
City
Mashhad
Province
Razavi Khorasan
Postal code
9177948564
Phone
+98 51 3800 2000
Email
habibiannezhadz971@mums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Taphaghodi, Mohsen
Street address
Deputy of Research and Technology, Ghorashi Building, next to Hoveyzeh Cinema, University Street
City
Mashhad
Province
Razavi Khorasan
Postal code
9138813944
Phone
+98 51 3841 1538
Email
tafaghodim@mums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad University of Medical Sciences
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
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Seyedeh Zhahra HabibianNejad
Position
Family Medicine Student
Latest degree
Medical doctor
Other areas of specialty/work
Family Physician
Street address
Mashhad University of Medical Sciences, Azadi square
City
Mashhad
Province
Razavi Khorasan
Postal code
9136964795
Phone
98 51 38049
Email
Habibiannezhadz971@mums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Seyedeh Zhahra HabibianNejad
Position
Family Medicine Student
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Medical doctor
Other areas of specialty/work
Family Physician
Street address
Azadi square, Mashhad University of Medical Science

City
Mashhad
Province
Razavi Khorasan
Postal code
9136964795
Phone
98 51 38049
Email
Habibiannezhadz971@mums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Seyedeh Zhahra HabibianNejad
Position
Family Medicine Student
Latest degree
Medical doctor
Other areas of specialty/work
Family Physician
Street address
Azadi square, Mashhad University of Medical Science
City
Mashhad
Province
Razavi Khorasan
Postal code
9136964795
Phone
98 51 38049
Email
Habibiannezhadz971@mums.ac.ir

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