

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 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 Covid 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- ABBB- 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

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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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Tafaghodi, Mohsen

Street address

Deputy of Research and Technology, Ghorashi Building, next to Hoveyeh Cinema, University Street

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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

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 Zahra HabibianNejad

Position

Family Medicine Student

Latest degree

Medical doctor

Other areas of specialty/work

Family Physician

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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