Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of the effectiveness of complementary therapy with Basil (Ocimum basilicum) capsule on the clinical symptoms of outpatients with COVID-19

Protocol summary

Study aim
Determining the effectiveness of basil extract in the treatment of outpatients Covid 19 and also evaluating its effects on reducing mortality or hospitalization due to (SARS-CoV-2)

Design
This is a double-blind clinical trial study of phase 2-3. This study will be performed on 140 patients who are divided into two groups. Randomly, one group of outpatients with Covid-19 was given a herbal supplement containing 300 mg of basil extract capsules and one group was given a placebo capsule for 2 weeks with common medications. The blocking method and Randomaize.com randomization site are used for randomization. During this period, patients are followed up for clinical symptoms and severity of the disease and the need for hospitalization.

Settings and conduct
This study is performed in 16-hour clinics of Covid-19 in Mashhad. In this study, the physician, patient, and data analyst are unaware of the medication.

Participants/Inclusion and exclusion criteria
Outpatients with COVID-19; Confirmation of RT-PCR test for SARS-CoV-2; Blood oxygen saturation more than 90%; Age 18-60 years;

Intervention groups
Placebo group: receiving common therapies + herbal medicine placebo (capsule containing microcellulose starch (Avisel) which is similar to the capsule of intervention groups) Intervention group: receiving common treatments + capsules of 600 mg of basil extract (300 mg twice a day)

Main outcome variables
The rate of recovery time from the time of randomization of patients to the improvement of clinical symptoms including fever, cough and myalgia; Paraclinical symptoms including leukopenia and CRP

General information

Reason for update
Unfortunately, due to technical problems in making the placebo and sampling, the start of the study was delayed.

Acronym

IRCT registration information
IRCT registration number: **IRCT20180103038199N4**
Registration date: **2021-04-24, 1400/02/04**
Registration timing: **prospective**

Last update: **2022-02-08, 1400/11/19**
Update count: **1**

Registration date
2021-04-24, 1400/02/04

Registrant information

Name
Vahid Reza Askari

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 51 3800 2264

Email address
askariv941@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-12-31, 1400/10/10

Expected recruitment end date
2023-01-20, 1401/10/30

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effectiveness of complementary therapy with Basil (Ocimum basilicum) capsule on the clinical symptoms of outpatients with COVID-19

Public title

Effect of Basil on outpatients with COVID-19

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Outpatients with COVID-19 Confirmed with RT-PCR SPO2 more than 90% Age between 18 to 60 years old

Exclusion criteria:

Pregnant women Breastfeeding women

Age

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

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **140**

Randomization (investigator's opinion)

Randomized

Randomization description

The volume of each block will be 4. Then write a list of blocks and assign numbers to them, for example (AABB (1) - BBAA (2) - BABA (3) - BAAB (4)) which according to the sample size of 140 people, we have 35 blocks. Then, random numbers between one and 35 are selected according to the Randomaize.com randomization site, and finally, the treatment allocation list is determined based on random numbers.

Blinding (investigator's opinion)

Double blinded

Blinding description

Due to the use of a placebo similar to interventional therapy, the physician associated with the participants and participants will not be informed of the assigned treatment and also the analyst will be unaware of the treatment assigned to the two groups. Finally, after analyzing the data, the researcher who prepared the packages reveals codes A and B.

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

Deputy of Research and Technology of the University, Qurashi Building, Next to Hoveyzeh Cinema, University Street

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Approval date

2021-01-30, 1399/11/11

Ethics committee reference number

IR.MUMS.REC.1399.597

Health conditions studied

1

Description of health condition studied

COVID-19 disease

ICD-10 code

U07.1

ICD-10 code description

COVID-19

Primary outcomes

1

Description

Time to recover from illness based on questionnaire

Timepoint

before intervention and 3, 7 and 14 days after beginning the intervention

Method of measurement

questionnaire

2

Description

Normalization of CRP and lymphopenia

Timepoint

before the intervention and 14 days after The beginning the intervention

Method of measurement

laboratory

Secondary outcomes

empty

Intervention groups

1

Description
Control group: Receive common treatments based on the ministry of health protocol + placebo capsules (Avicell) made in Mashhad school of Persian and complementary medicine twice a day for 10 days
Category
Placebo

2

Description
Intervention group: Receive common treatments based on the ministry of health protocol + capsules containing 300 mg of basil extract made in Mashhad school of Persian and complementary medicine 2 times a day for 10 days
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
مراکز 16 ساعته کرونا
Full name of responsible person
دکتر وحید رضا عسکری
Street address
Mashhad university of medical science, Azadi square
City
Mashhad
Province
Razavi Khorasan
Postal code
9177948564
Phone
+98 51 3800 2000
Email
askariv@mums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr Mohsen Tafaghodi
Street address
Deputy of Research and Technology of the University , Qurashi Building, Next to Hoveyzeh Cinema, University Street
City
Mashhad
Province
Razavi Khorasan
Postal code
9138813944
Phone
+98 51 3841 2081
Email
ramresearch@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
Dr Vahid Reza Askari
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
Street address
Faculty of Medicine, Azadi sq, Mashhad
City
Mashhad
Province
Razavi Khorasan
Postal code
9177948564
Phone
+98 915 371 9688
Email
askariv@mums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr Vahid Reza Askari
Position
Assistant Professor
Latest degree

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Other areas of specialty/work

Medical Pharmacy

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Person responsible for updating data

Contact

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Mashhad University of Medical Sciences

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Dr Vahid Reza Askari

Position

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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

No - There is not 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