Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of the effectiveness of Silymarin (Silybum marianum) capsule on the clinical symptoms of outpatients with COVID-19

Protocol summary

Study aim

Determining the effectiveness of Silymarin (Silybum marianum) extract capsule 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 study of phases 2-3. This study will be performed on 140 patients who are divided into two groups. Randomly, a group of outpatients with Covid-19 were given a herbal supplement containing 500 mg capsules of Silymarin (Silybum marianum) extract three times a day and a group of placebo capsules for 10 days with common medications. The blocking method and randomization site "Randomaize.com" are used for randomization. Patients are followed up during this period in terms of clinical symptoms and severity of the disease and the need for hospitalization.

Settings and conduct

This study is performed in 16-h clinics of Covid-19 in Mashhad. Physician, patient, and data analyst are unaware of the medication.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Outpatients with COVID-19; Confirming RT-PCR test for SARS-CoV-2; Blood oxygen saturation more than 90%; Age 18-60 years Exclusion criteria: Pregnant women; Breastfeeding women

Intervention groups

Placebo group: Receive common therapies + herbal medicine placebo (capsule containing microcellulose starch (Avisel), which is similar to the capsule of the intervention groups and is prepared in the School of Persian and Complementary Medicine of Mashhad University of Medical Sciences) three times a day / Intervention group: Receive common treatments + 500 mg capsules of Silymarin (Silybum marianum) extract prepared in the School of Persian and Complementary Medicine, Mashhad University of Medical Sciences three times 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

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180103038199N10**
Registration date: **2022-01-24, 1400/11/04**
Registration timing: **prospective**

Last update: **2022-01-24, 1400/11/04**
Update count: **0**

Registration date

2022-01-24, 1400/11/04

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

2022-02-20, 1400/12/01

Expected recruitment end date

2023-03-19, 1401/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effectiveness of Silymarin (Silybum marianum) capsule on the clinical symptoms of outpatients with COVID-19

Public title

Silymarin capsule in 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
- Care provider
- Outcome assessor

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

2021-09-07, 1400/06/16

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1400.414

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 10 days after beginning the intervention

Method of measurement

Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Control group: Receive common therapies + herbal medicine placebo (capsule containing microcellulose starch (Avisel), which is similar to the capsule of the intervention groups and is prepared in the School of Persian and Complementary Medicine of Mashhad University of Medical Sciences) three times a day

Category

Placebo

2

Description
Intervention group: Receive common treatments + 500 mg capsules of Silymarin (Silybum marianum) extract prepared in the School of Persian and Complementary Medicine, Mashhad University of Medical Sciences three times a day
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Clinics affiliated to Mashhad University of Medical Sciences
Full name of responsible person
Dr Vahid Reza Askari
Street address
Mashhad University of Medical Science, Azadi Square
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Deputy of Research and Technology of the University , Qurashi Building, Next to Hoveyzeh Cinema, University Street
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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
Vahid Reza Askari
Position
Assistant professor of clinical pharmacology
Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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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