

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparing the efficacy of Allicin derivatives capsule and Placebo as an adjuvant for patients with COVID-19: A double-blind randomized placebo controlled clinical trial

Protocol summary

Study aim

Evaluation of Allicin derivatives capsule efficacy as an adjuvant therapy for patients with COVID-19

Design

Randomized, parallel group trial with blinded outcome assessment on 25 patients. Randomization was done using online website (randomization.com)

Settings and conduct

The study will be done at Internal ward, Imam Reza Hospital, Mashhad. Medication and Placebo will be coded by researcher. Randomization will be done using online website (randomization.com). The participants (patients with COVID-19), Physician and nurses who evaluates the patients will be blinded to the group allocation. Allicin derivatives capsules and Placebo have the same color, shape and size.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients diagnosis with COVID-19; Age between 18-70 year old. Non-inclusion criteria: breastfeeding or pregnancy; Allergy to Onion or Garlic; History of recent surgery or digestive tract bleeding

Intervention groups

Intervention group: Administration of Allicin derivatives capsule (90 mg) twice per day for 14 days plus the standard treatment for COVID-19. Control group: Administration of Placebo twice per day for 14 days plus the standard treatment for COVID-19.

Main outcome variables

Time to full recovery; Body temperature; O2 saturation

General information

Reason for update

Due to the removal of one of the colleagues from the collaboration and mistakes in recording some information such as sample size

Acronym

IRCT registration information

IRCT registration number: **IRCT20200610047722N1**

Registration date: **2020-07-07, 1399/04/17**

Registration timing: **registered_while_recruiting**

Last update: **2021-03-29, 1400/01/09**

Update count: **2**

Registration date

2020-07-07, 1399/04/17

Registrant information

Name

Saeedeh Ebrahimpour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3882 3251

Email address

s_ebrahimpour2008@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-21, 1399/04/01

Expected recruitment end date

2020-07-22, 1399/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the efficacy of Allicin derivatives capsule and Placebo as an adjuvant for patients with COVID-19: A

double-blind randomized placebo controlled clinical trial

Public title

Effect of Allicin derivatives capsule in treatment of patients with new Coronavirus

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with RT-PCR positive for SARS-CoV-2 , clinical sign and symptoms (fever, cough and myalgia) and CT scan indicate COVID-19 positive. Age 18-70 Sign consent form

Exclusion criteria:

History of allergic reaction to Allicin History of allergic reaction to Garlic or Onion History of low blood pressure or gastrointestinal tract bleeding Low blood pressure and the beginning of study (lower than 120/80 mmHg) Patients with immune deficiency disorders (patients undergo chemotherapy, organ or bone marrow transplants and patients with autoimmune disease) No need to use ventilator during the study Unable to swallow the oral medication Pregnancy Breastfeeding

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

0

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **25**

Randomization (investigator's opinion)

Randomized

Randomization description

Random allocation to study groups including intervention and placebo will be done using online randomization website (randomization.com). This website will allocate the patients (100) into both medication and placebo groups with the same sample size. The numbers will be produced in a row (between 1-100) for both medication and placebo groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

Medication and placebo will be coded by the researcher. Allicin derivatives capsules and Placebo have the same color, shape and size; so participants, physicians and nurses who evaluate the results are blinded to the intervention and groups allocation.

Placebo

Used

Assignment

Parallel

Other design features

No

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

Daneshgah St, Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Approval date

2020-06-06, 1399/03/17

Ethics committee reference number

IR.MUMS.REC.1399.289

Health conditions studied

1

Description of health condition studied

COVID-19

ICD-10 code

U07.2

ICD-10 code description

COVID-19, virus not identified

2

Description of health condition studied

COVID-19

ICD-10 code

U07.1

ICD-10 code description

COVID-19, virus identified

Primary outcomes

1

Description

Body temperature

Timepoint

Before starting the study and every day during the study

Method of measurement

Thermometer

2

Description

O2 saturation

Timepoint

Before starting the study and every day during the study

Method of measurement

pulse oximeter

3

Description

Time to recovery

Timepoint

Everyday until the full recovery

Method of measurement

WHO criteria for COVID-19

Secondary outcomes

1

Description

Lymphocytopenia

Timepoint

Before starting the study, one week and two week later

Method of measurement

Cell Counter (CBC)

2

Description

C-reactive protein

Timepoint

Before starting the study, one week and two week later

Method of measurement

C-RP kit

3

Description

Serious side effects

Timepoint

Before starting the study and everyday during the study

Method of measurement

questionnaire

Intervention groups

1

Description

Intervention group: Standard treatment for COVID-19 plus Allicin derivatives capsule (90 mg) twice per day for 14 days

Category

Treatment - Drugs

2

Description

Control group: Standard treatment for COVID-19 plus Placebo twice per day for 14 days

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital-Mashhad

Full name of responsible person

Amir Masoud Hashemian

Street address

Emam Reza hospital, Ebn Sina street

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913316

Phone

+98 51 3854 3031

Email

HashemianAM@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hossein Nik Tale

Full name of responsible person

Hossein Nik Tale

Street address

Ghoreishi building; Daneshgah street

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Phone

+98 51 3841 1538

Email

hoseen.nikta@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Hossein Nik Tale

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Persons

Person responsible for general inquiries

HashemianAM@mums.ac.ir

Contact

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Amir Masoud Hashemian
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Emergency Medicine
Street address
Emam Reza hospital, Ebn Sina street
City
Mashhad
Province
Razavi Khorasan
Postal code
9137913316
Phone
+98 51 3854 3031
Email
hashemianam@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Amir Masoud Hashemian
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Emergency Medicine
Street address
Ebn Sina street
City
Mashhad
Province
Razavi Khorasan
Postal code
9137913316
Phone
+98 51 3854 3031
Email

Person responsible for updating data

Contact

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Amir Masoud Hashemian
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Emergency Medicine
Street address
Ebn Sina street
City
Mashhad
Province
Razavi Khorasan
Postal code
9137913316
Phone
+98 51 3854 3031
Email
hashemianam@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