Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 that 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
۹۱۳۷۹۱۳۳۱۶
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

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
۹۱۳۷۹۱۳۳۱۶

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
۹۱۳۷۹۱۳۳۱۶

Phone
+98 51 3854 3031

Email
HashemianAM@mums.ac.ir

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
۹۱۳۷۹۱۳۳۱۶

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