Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of chitosan supplementation on clinical symptoms in patients with COVID-19

Protocol summary

Study aim
The effect of chitosan supplementation on clinical symptoms in patients with COVID-19

Design
The 80 eligible participants in the phase 2 clinical trial are randomly assigned to either the chitosan group or the placebo group. Patients will be divided into 2 equal groups using the block randomization method with 4 and 8 block sizes. Sealed envelope online software will be used for randomization.

Settings and conduct
Patients with coronavirus will be recruited from the Amir Almomenin hospital in Arak. The participant's assignment will be concealed from all participants and investigators, except for the study epidemiologist.

Participants/Inclusion and exclusion criteria
Inclusion criteria: age between 20 to 75 years, willingness to participate with written informed consent, diagnosis of coronavirus based on the PCR test. Exclusion criteria: current use of warfarin, presence of sensitivity to seafood.

Intervention groups
Intervention 1: receive 10 cc of the same 2.5% chitosan syrup (250 mg pharmacological grade chitosan) during the day, for 2 weeks.All syrups are prepared by the Barij Essence Pharmaceutical Co., Kashan, Iran.

Main outcome variables
Respiration rate; Chest CT scan; High sensitivity C-reactive protein; Erythrocyte sedimentation rate; Severity and number of coughs; Body temperature; Alanine aminotransferase activity; aspartate aminotransferase activity; Albumin.

General information

Reason for update
The change in application form of chitosan

Acronym

IRCT registration information
IRCT registration number: **IRCT20210510051243N1**
Registration date: **2021-05-25, 1400/03/04**
Registration timing: **prospective**

Last update: **2022-02-19, 1400/11/30**
Update count: **1**

Registration date
2021-05-25, 1400/03/04

Registrant information

Name
Hamid Abtahi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 86 3417 3502

Email address
abtahi@arakmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-05-31, 1400/03/10

Expected recruitment end date
2021-12-22, 1400/10/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of chitosan supplementation on clinical symptoms in patients with COVID-19

Public title
Chitosan supplementation and Coronavirus

Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Age between 20 to 75 years, Willingness to participate with written informed consent, Diagnosis of coronavirus based on the PCR test.
Exclusion criteria:
Current use of warfarin, Presence of sensitivity to seafood.
Age
From **20 years** old to **75 years** old
Gender
Both

Phase
2
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients will be randomly assigned to two groups. To do this, they will be divided into 2 equal groups by permuted block randomization method with 4 and 8 block sizes. The online Sealed envelope site will be used in such a way that the randomization sequence is generated by the mentioned method and a unique code is assigned to each of them. The randomization sequence will remain with the epidemiologist colleague, and patients will be assigned to the intervention and control groups, respectively, in accordance with the randomization sequence.
Blinding (investigator's opinion)
Double blinded
Blinding description
This study will be done as a double blinded study. To blind the participants, a placebo that is similar in color, smell, taste, shape, size and weight to the main drug will be used. The outcomes will be assessed by a person who is unaware of assigning individuals to groups. The drugs will be provided to the researcher and the patient in similar packages, each of which has a unique code. At the end of the study, the decoding process is performed based on the randomization sequence and unique codes of each individual.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Arak University of Medical Sciences
Street address
Medical and Molecular Research Center, School of Medicine, Pardis site of University of Medical Sciences, Basij Square, Arak city
City
Arak
Province
Markazi
Postal code
3848176341
Approval date
2021-04-28, 1400/02/08
Ethics committee reference number
IR.ARAKMU.REC.1400.016

Health conditions studied

1

Description of health condition studied
COVID-19 infection
ICD-10 code
U07.1
ICD-10 code description
COVID-19; virus identified

Primary outcomes

1

Description
Respiratory Rate
Timepoint
day 1 and day 14
Method of measurement
The number of breaths a person takes per minute

2

Description
Severity of lung involvement
Timepoint
day 1 and day 14
Method of measurement
Chest CT scan

3

Description
High-sensitivity C-reactive protein
Timepoint
Day 1 and day 14.
Method of measurement
Colorimetric method

4

Description
Erythrocyte Sedimentation Rate
Timepoint
Day 1 and day 14
Method of measurement
Colorimetric method

5

Description
Severity and number of coughs
Timepoint
Day 1 and day 14
Method of measurement
Cough visual analogue scale (VAS)

6

Description
Body temperature
Timepoint
Day 1 and day 14
Method of measurement
Clinical Thermometer

7

Description
Alanine aminotransferase Activity
Timepoint
Day 1 and day 14
Method of measurement
Colorimetric method

8

Description
Aspartate aminotransferase Activity
Timepoint
Day 1 and day 14
Method of measurement
Colorimetric method

9

Description
Superoxide dismutase Activity
Timepoint
Day 1 and day 14
Method of measurement
Colorimetric method

10

Description
Albumin
Timepoint
Day 1 and day 14
Method of measurement
Colorimetric method

11

Description
Death outcome
Timepoint
Day 14
Method of measurement
Percentage of fatal patients in two groups

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: receive 10 cc of the same 2.5% chitosan syrup (250 mg pharmacological grade chitosan) during the day, for 2 weeks.All syrups are prepared by the Barij Essence Pharmaceutical Co., Kashan, Iran.
Category
Treatment - Drugs

2

Description
Control group: Participants in the control group will receive 10 cc of identical placebo syrup (CMC with the same viscosity of chitosan syrup) during the day, for 2 weeks. All syrups are prepared by the Barij Essence Pharmaceutical Co., Kashan, Iran.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Arak Amir Almomenin hospital
Full name of responsible person
Hamid Abtahi
Street address
Medical and Molecular Research Center, School of Medicine, Pardis site of University of Medical Sciences, Basij Square, Arak city
City
Arak
Province
Markazi
Postal code
3848176341
Phone
+98 86 3417 3502
Email
abtahi@arakmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Arak University of Medical Sciences

Full name of responsible person
Hamid Abtahi

Street address
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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
Arak 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
Arak University of Medical Sciences

Full name of responsible person
Hamid Abtahi

Position
Professor

Latest degree
Ph.D.

Other areas of specialty/work
Microbiology

Street address
Medical and Molecular Research Center, School of Medicine, Pardis site of University of Medical Sciences, Basij Square, Arak city

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is 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
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
The non-identifiable individual participant data collected in this study will be shared. Also, The protocol, results, and statistical analysis of the current study will be published in the relevant articles.

When the data will become available and for how long
The non-identifiable individual participant data will become available after the publication of the relevant articles.

To whom data/document is available
The non-identifiable individual participant data will become available to other researchers in academic institutions.

Under which criteria data/document could be used
The non-identifiable individual participant data can only be used for research.

From where data/document is obtainable
The non-identifiable individual participant data will be obtainable by sending an e-mail to Dr. Hamid Abtahi (Email: abtahi@arakmu.ac.ir).

What processes are involved for a request to access data/document
Other researchers in academic institutions can send their request by e-mail to Dr. Hamid Abtahi (Email: abtahi@arakmu.ac.ir). The data will be sent to them after consulting and approving the research team.

Comments