Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

Effect of the combination of BCc1 & Hep-S on the improvement of clinical & laboratory symptoms of hospitalized COVID-19 patients in a randomized, double-blind, clinical trial

Protocol summary

Study aim

Evaluating the effect of the combination of BCc1 & Hep-S on the improvement of clinical & laboratory symptoms of hospitalized COVID-19 patients

Design

Clinical trial involving a control group with parallel , double blind groups randomized according to block randomization form at phases 1&2 on 120 patients

Settings and conduct

- Place: wards for hospitalized COVID-19 patients - Method: by blinding the patients and the clinician

Participants/Inclusion and exclusion criteria

Inclusion criteria: hospitalized definite COVID-19 patients diagnosed via PCR & CT scan of the lungs, patients' filling out a consent form, patients won't be discharged within 48 hrs, patients' conditions won't be improving within 48 hrs Exclusion criteria: pregnancy, in lactation, patients with transplants, hereditary immunodeficiency, patients with a record of type 1 diabetes, addiction to alcohol or drugs

Intervention groups

1. Hospitalized COVID-19 patients: the patients would receive the standard COVID-19 regimen along with BCc1 nanomedicine in 3 servings per day according to the presented dosage. 2. Hospitalized COVID-19 patients: the patients would receive the standard COVID-19 regimen along with Hep-s in 3 servings per day according to the presented dosage. 3. Hospitalized COVID-19 patients: the patients would receive the standard COVID-19 regimen along with the combination of BCc1 & Hep-s in 3 servings per day according to the presented dosage. 4. Hospitalized COVID-19 patients: the patients would receive the standard COVID-19 regimen along with placebo in 3 servings per day according to the presented dosage.

Main outcome variables

Hospitalization period, morality, CT scan images of the lungs,

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170731035423N2**
Registration date: **2020-06-12, 1399/03/23**
Registration timing: **registered_while_recruiting**

Last update: **2020-10-21, 1399/07/30**
Update count: **1**

Registration date

2020-06-12, 1399/03/23

Registrant information

Name

Maryam Hafizi

Name of organization / entity

Cancer Research Centre, Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-21, 1399/03/01

Expected recruitment end date

2021-03-20, 1399/12/30

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of the combination of BCc1 & Hep-S on the improvement of clinical & laboratory symptoms of hospitalized COVID-19 patients in a randomized, double-blind, clinical trial

Public title
Effect of the combination of BCc1 & Hep-S on hospitalized COVID-19 patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Hospitalized definite COVID-19 patients diagnosed by PCR & CT scan of the lungs Patients' filling out a consent form Patients won't be discharged within 48 hrs Patients' conditions won't be improving within 48 hrs
Exclusion criteria:
Pregnancy In lactation Addiction to alcohol or drugs Patients with transplants Patients with a record of type 1 diabetes Hereditary immunodeficiency
Age
From **20 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
A random number table would be used for randomization. Therapeutic regimens would be classified into 4 groups of A, B, C and D. We start from the first number on the right side of the table and move downward. If the first number on the right is 1 & 2, we prescribe regimen A, if it is 3 & 4, regimen B, if it is 5 & 6, regimen C, and if it is 7 & 8, regimen D. In case the number is 9 or 0, we leave them and consider the next number. We continue doing this until the sample size of the group is complete, and then move forward to the next group.
Blinding (investigator's opinion)
Double blinded
Blinding description
The medical staff (doctors & nurses), the researcher and the clinician would be blinded by labeling the syrup bottles with unidentified content. The physician who provides the patients with the syrup bottles would be unaware of the content and randomly assign the patients to 4 groups through pre-designed block randomization form.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Shahid Beheshti University of Medical Sciences
Street address
Shohadaye Tajrish Hospital, Shahrdari St., Tajrish Sq.
City
Tehran
Province
Tehran
Postal code
1985717443
Approval date
2020-05-07, 1399/02/18
Ethics committee reference number
IR.SBMU.CRC.REC.1399.001

Health conditions studied

1

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

Primary outcomes

1

Description
Hospitalization period
Timepoint
Hospitalization period
Method of measurement
Counting hospitalization days

2

Description
Mortality
Timepoint
Before and after being released

Method of measurement
Observation

3

Description
CT scan images of the lungs
Timepoint
Before hospitalization & 2 weeks after
Method of measurement
CT scan images

4

Description
Clinical indices
Timepoint
Before intervention, 3 & 6 days after intervention and before being released
Method of measurement
Questionnaire

5

Description
CT scan of the lungs
Timepoint
Before the start of the intervention, before being released & 2 weeks after
Method of measurement
CT scan machine

Secondary outcomes

1

Description
CRP
Timepoint
Before intervention, 3 & 6 days after intervention and before being released
Method of measurement
Biochemical methods

2

Description
ESR
Timepoint
Before intervention, 3 & 6 days after intervention and before being released
Method of measurement
Biochemical methods

3

Description
Oxygen saturation in patients
Timepoint
Before intervention, every day after intervention and before being released
Method of measurement
Pulse oximetry

4

Description
CBC
Timepoint
Before intervention, 3 & 6 days after intervention and before being released
Method of measurement
Biochemical methods

5

Description
SGOT & SGPT enzymes
Timepoint
Before intervention & before being released
Method of measurement
Biochemical methods

6

Description
PCR test
Timepoint
Before intervention & before being released
Method of measurement
Molecular methods

Intervention groups

1

Description
Intervention group 1 – Medicine: chelated mixture named BCc1. Number & content: a 250 cc bottle containing 200 cc medicine in the form of syrup. Chemical mixture: polymerized organic acid using nanochelating technology. Density: 500 mg of chelated mixture per 2 cc. Consumption dose: 3 servings per day (4 cc per serving). Direction for use: the consumption dose per serving should be diluted in 250 cc of water and consumed orally. Equipment: no special equipment is required. Patients will be provided with the medicine placed in 250 cc bottles along with a sterilized 15 cc falcon tube to measure the consumption dose. Consumption duration: hospitalization period. Manufacturing company: laboratory of Sodour Ahrar Shargh Knowledge-based Company.
Category
Treatment - Drugs

2

Description
Intervention group 2 – Medicine: chelated selenium mixture named Hep-s. Number & content: a 250 cc bottle containing 200 cc medicine in the form of syrup. Chemical mixture: polymerized organic acid using nanochelating technology. Density: 500 µg of chelated selenium mixture per 2 cc. Consumption dose: 3 servings per day. 12 cc on the first 3 days and 6 cc from day 4 onwards. Direction for use: the consumption dose per serving should be diluted in 250 cc of water and

consumed orally. Equipment: no special equipment is required. Patients will be provided with the medicine placed in 250 cc bottles along with a sterilized 15 cc falcon tube to measure the consumption dose. Consumption duration: hospitalization period. Manufacturing company: laboratory of Sodour Ahrar Shargh Knowledge-based Company.

Category

Treatment - Drugs

3

Description

Intervention group 3 – Medicine: a package of BCc1 & Hep-s. Number & content: two separate 250 cc bottles for BCc1 & Hep-s, each containing 200 cc medicine in the form of syrup. Chemical mixture: polymerized organic acid using nanochelating technology. Density: 500 mg of chelated mixture per 2 cc for BCc1 & 500 µg of chelated selenium mixture per 2 cc for Hep-s. Consumption dose: 2 servings per day for BCc1 (6 cc per serving). One serving per day for Hep-s (12 cc on the first 3 days and 6 cc from day 4 onwards). Direction for use: the consumption dose per serving should be diluted in 250 cc of water and consumed orally. Equipment: no special equipment is required. Patients will be provided with the medicine placed in 250 cc bottles along with a sterilized 15 cc falcon tube to measure the consumption dose. Consumption duration: hospitalization period. Manufacturing company: laboratory of Sodour Ahrar Shargh Knowledge-based Company.

Category

Treatment - Devices

4

Description

Control group – Medicine: ORS powder. Number & content: a 250 cc bottle containing 200 cc placebo in the form of syrup. Chemical mixture: glucose & sodium bicarbonate. Density: 50 mg ORS per 2 cc. Consumption dose: 3 servings per day. 2 cc per serving. Direction for use: the consumption dose per serving should be diluted in 250 cc of water and consumed orally. Equipment: no special equipment is required. Patients will be provided with the medicine placed in 250 cc bottles along with a sterilized 15 cc falcon tube to measure the consumption dose. Consumption duration: hospitalization period. Manufacturing company: Rouz Darou Company.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohadaye Tajrish Hospital

Full name of responsible person

Mohammad Esmaeil Akbari

Street address

Shohadaye Tajrish Hospital, Shahrdari St., Tajrish Sq.

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2

Recruitment center

Name of recruitment center

Masih Daneshvari Hospital

Full name of responsible person

Mohammadreza Hashemian

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Masih Daneshvari Hospital, Darabad Avenue, Shahid Bahonar roundabout,

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences, Cancer Research Center

Full name of responsible person

Atieh akbari

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Shohadaye Tajrish Hospital, Shahrdari St., Tajrish Sq.

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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
Shahid Beheshti University of Medical Sciences, Cancer Research Center
Proportion provided by this source
50
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

2

Sponsor
Name of organization / entity
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Full name of responsible person
Somayh Kalanaky
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No.1, Afshin Alley, Abdollahzadeh St., Keshavarz Blvd., Tehran, Iran.
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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
Sodour Ahrar Shargh Knowledge-based Company
Proportion provided by this source
50
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
Other

Person responsible for general inquiries

Contact
Name of organization / entity
Sodour Ahrar Shargh Knowledge-based Company
Full name of responsible person
Maryam Hafizi
Position
Senior R&D expert
Latest degree
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Other areas of specialty/work
Medical Biotechnology
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Other areas of specialty/work
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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
Not applicable
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
The patients' CRF will be published.
When the data will become available and for how long
After completing the project
To whom data/document is available
Only for researchers working in academic & scientific institutes
Under which criteria data/document could be used
Upon request & if approved by the researcher in charge
From where data/document is obtainable
Via sending an email to the senior R&D expert at Sodour Ahrar Shargh Knowledge-based Company: mhafizi@nanochelatingtechnology.com
What processes are involved for a request to access data/document
The documents, including information forms, reports, analyses results and statistical results, are kept by the researcher in charge. A request for data or documents should be emailed to the senior R&D expert (email address: m.hafizi6060@nanochelatingtechnology.com). Then, within 72 working hours and upon the approval of the request by the researcher in charge, the requested documents would be sent to the requester.
Comments