Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 Jul 2026

Comparison of three methods of treatment in patients with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) with and without coronavirus positive test (Kovid-19)

Protocol summary

Study aim
Overall objective: comparison of three therapies in patients with Super Acute Respiratory Syndrome with and without corona testing for a positive virus

Design
Clinical trial with control group, with parallel, two-way blind groups, randomized to 30 patients, random number table was used for randomization.

Settings and conduct
After the approval of the plan in the University Research Council and obtaining the code of ethics, sampling will begin among patients who have the conditions to participate in the study. First, randomization will be performed and then individuals will be randomly divided into 3 groups. The study will be blinded in two ways. Vitamin D and C levels are measured in all three groups before the intervention, and patients who are deficient will be included in the study. Then, we will select patients with vitamin D and C deficiency and treat them with vitamin D and vitamin C supplements, and we will study the patient as a control group among other patients who did not have vitamin deficiency. We will examine the rate of recovery in untreated patients with vitamin D and C according to the checklist.

Participants/Inclusion and exclusion criteria
Inclusion criteria: the patient was admitted to the acute respiratory center; consent to participate in the study; age 15 years and older. Exclusion criteria: the patient has lung cancer; patients undergoing chemotherapy and radiotherapy.

Intervention groups
Group one: taking vitamin D supplements and routine treatment under the supervision of an infectious disease specialist, group two: taking vitamin C supplements and routine treatment under the supervision of an infectious disease specialist and the third group:receiving routine treatment under the supervision of a specialist. Infections are classified as control groups.

Main outcome variables
Vitamin D; Vitamin C; RT-PCR results; CT-Scan findings; CX-Ray Findings; CBC; Vital signs; Respiratory Symptoms

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20140305016852N4**
Registration date: **2020-05-04, 1399/02/15**
Registration timing: **registered_while_recruiting**

Last update: **2020-05-04, 1399/02/15**
Update count: **0**

Registration date
2020-05-04, 1399/02/15

Registrant information

Name
somayyeh nayyeri

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 51 5222 9202

Email address
s.nayyeri86@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-04-20, 1399/02/01

Expected recruitment end date
2020-09-21, 1399/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of three methods of treatment in patients with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) with and without coronavirus positive test (Kovid-19)

Public title

Comparison of three methods of treatment in patients with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) with and without coronavirus positive test

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The patient was admitted to the acute respiratory center Consent to participate in the study Age 15 to above Do not take vitamin C and D supplements No gout Lack of kidney and liver disease No pregnancy or lactation No treatment with anti convulsants

Exclusion criteria:

The patient has lung cancer Patients undergoing chemotherapy and radiotherapy If the patient dies If the patient has a decreased level of consciousness If the patient does not want to continue working on the plan

Age

From **15 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

A random number table is used to randomize. To use the table of random numbers, first to read the numbers of the table will be determined, then the numbers will be considered for different groups. We touch on one of the numbers and move in one of the predefined directions and assign the numbers to different groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

The study will be blinded in two ways. Patients will be blinded by the type of intervention, and the researcher who has to enter the data in the relevant checklist will be blinded by the type of intervention.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of sabzevar University of Medical Sciences

Street address

Deputy of Research and Technology-Campus of the University of Medical Sciences-above the memory of the shohadaye gomnam-shohadaye hasteii Boulevard-Sabzevar

City

Sabzevar

Province

Razavi Khorasan

Postal code

9617913112

Approval date

2020-04-19, 1399/01/31

Ethics committee reference number

IR.MEDSAB.REC.1399.015

Health conditions studied

1

Description of health condition studied

Coronavirus disease (covid-19)

ICD-10 code

B97.29

ICD-10 code description

Other coronavirus as the cause of diseases classified elsewhere

Primary outcomes

1

Description

Complete recovery of clinical symptoms of 2019 disease

Timepoint

About a week after starting treatment

Method of measurement

Clinical and laboratory questionnaire

2

Description

Normalization of chest symptoms in CT scan.

Timepoint

About 7 to 14 days after starting treatment

Method of measurement

CT scan result

Secondary outcomes

1

Description
Improving and normalizing the level of laboratory symptoms
Timepoint
At least 1 to 2 weeks after starting treatment
Method of measurement
Laboratory techniques

Intervention groups

1

Description
Intervention group: In this group, untreated COVID-19 patients are treated with routine treatments and 50,000 units of vitamin D daily for one week.
Category
Treatment - Drugs

2

Description
Intervention group: In this group, untreated COVID-19 patients are treated with routine and vitamin C-containing treatments containing 500 mg daily for one week.
Category
Treatment - Drugs

3

Description
Control group: The control group includes patients who are under routine care only.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Vasei Educational and Medical Center
Full name of responsible person
Ebrahim Shirzade
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Vasei hospital , Shohadaye Hasteii Blvd , Sabzevar
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Sabzevar University of Medical Sciences
Full name of responsible person
Fereshteh Ghorat
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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
Sabzevar 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
Sabzevar University of Medical Sciences
Full name of responsible person
Ebrahim Shirzade
Position
Faculty member
Latest degree
Subspecialist
Other areas of specialty/work
Ophthalmology
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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
Yes - There is a plan to make this available
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
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Clinical information (including therapeutic outcomes), laboratory and demographic of Coronavirus patients 2019 under treatment with routine and vitamin D and C
When the data will become available and for how long
About 5 to 10 months after the start of the study
To whom data/document is available
Public
Under which criteria data/document could be used
Careful study information can be provided to qualified researchers interested in treating patients.
From where data/document is obtainable
Corresponding author
What processes are involved for a request to access data/document
Competent and enthusiastic researchers can receive data documentation from the responsible author after presenting the work by presenting their academic information and identification.
Comments
The clinical trial, titled "Comparison of three therapies in patients with super-acute respiratory syndrome (SARS-COV-2) with and without positive coronavirus testing (Covid-19)", has not been previously reported elsewhere. Not sent elsewhere. We are very happy to have registered our clinical trial on the IRCT website (www.irct.ir). thank you. Wishing you good health and happy moments