Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effects of organic boron - sugar complex (as Calcium Fructoborate) supplement on the severity and consequences of COVID-19 in inpatient cases: A double blind Clinical Trial

Protocol summary

Study aim
Effects of organic boron - sugar complex (as Calcium Fructoborate) supplement on the severity and consequences of COVID-19 in inpatient cases.

Design
Clinical trial with control group with parallel groups, phase 2 on 300 patients

Settings and conduct
This study will performed on confirmed Covid-19 patients in Bu Ali Sina and Velayat hospitals in Qazvin. All patients will receive standard treatment based on recommendations of the national COVID-19 treatment guidelines. In the intervention group, calcium fructoborate solution and in the control group, placebo solution with similar taste, color and appearance will be given and the mortality rate and length of hospital stay will be recorded and compared.

Participants/Inclusion and exclusion criteria
Inclusion criteria: definitive cases of Covid-19 confirmed by positive PCR test on nasopharyngeal secretions. Exclusion criteria: Age younger than 19 or older than 80 years old. Suspected to have bacterial respiratory infections in the beginning of study Suffering from serious chronic diseases pregnancy Receiving drugs that are not recommended in national guidelines for COVID-19 treatment (including steroids higher than dexamethasone 8 mg daily equivalent, IVIG, plasmaphresis, serum therapy, hemoperfusion, pirfinidone) during the study period for any reason.

Intervention groups
Drug group: Patients receiving standard diet of Covid 19 plus a syrup containing organic-sugar boron complex (as calcium fructoborate) containing 430 mg in 5 ml Placebo group: Ppatients receiving the standard treatment regimen for Covid 19 plus placebo syrup with the same color and taste as the calcium fructoborate syrup

Main outcome variables
Mortality rate and length of hospital stay

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20090803002276N4**
Registration date: **2021-10-29, 1400/08/07**
Registration timing: **prospective**

Last update: **2021-10-29, 1400/08/07**
Update count: **0**

Registration date
2021-10-29, 1400/08/07

Registrant information

Name
Behzad Bijani

Name of organization / entity
Qazvin University of Medical sciences

Country
Iran (Islamic Republic of)

Phone
+98 28 1335 4808

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bbijani@qums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-11-01, 1400/08/10

Expected recruitment end date
2022-01-30, 1400/11/10

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of organic boron - sugar complex (as Calcium Fructoborate) supplement on the severity and consequences of COVID-19 in inpatient cases: A double blind Clinical Trial

Public title

Evaluation of impact of Calcium Calcium Fructoborate in patients admitted with the diagnosis of COVID19 infection.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Admission in the hospital with a positve PCR test for COVID-19 Age between 19 and 80 years

Exclusion criteria:

Patients suspected to bacterial infections in the first day of admission suffering severe chronic diseases pregnancy consumption of medications not recommended in national COVID-19 guideline.

Age

From **19 years** old to **80 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **300**

Randomization (investigator's opinion)

Randomized

Randomization description

Random allocation rule is used for allocation of patients to intervention and control groups. one hundred fifty pieces of paper will be marked as intervention and control and placed in a bag. In the first day of admission, one of papers is pulled out randomly and according to the word written on the paper, the participant will be placed in one of the two groups. Neither the patient nor the chief researcher will be notified of their assignment to the groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

During the process of allocation of patients to intervention and placebo groups, only the clinical caregivers will be notified of the individual's allocation to the drug or placebo group. There is no difference between the drug and the placebo in terms of shape and taste and the patient will not notice his/her group at all. Outcome assessors also do not know to what group each patient belongs to. Statistical analysts and authors of the draft article, identify the patients only by a number and their name will remain completely unknown to them.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Qazvin University of Medical Sciences

Street address

Research deputy of Qazvin University of Medical Sciences, first alley, Maveddat St, Shaheed Beheshti Blvd

City

Qazvin

Province

Qazvin

Postal code

۳۴۱۵۶۱۳۹۱۱

Approval date

2021-09-18, 1400/06/27

Ethics committee reference number

IR.QUMS.REC.1400.260

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

Mortality rate

Timepoint

from including to study to 30 days

Method of measurement

Observation

2

Description

Hospital stay

Timepoint

After discharge

Method of measurement

Patient hospital record

Secondary outcomes

1

Description

Arterial Oxygen Saturation

Timepoint

Daily

Method of measurement

Pulse oxymeter device

2

Description

Respiratory rate

Timepoint

Daily

Method of measurement

Counting the number of breaths per minute

3

Description

Leukocyte count

Timepoint

Every three days

Method of measurement

Cell counter device

4

Description

Lymphocyte percentage

Timepoint

Every three days

Method of measurement

Cell counter device

5

Description

Serum electrolites

Timepoint

Every three days

Method of measurement

Flame photometer device

6

Description

Quantitative C reactive Protein

Timepoint

Every three days

Method of measurement

Turbidometer device

Intervention groups

1

Description

Intervention group: Standard therapeutic regimen for COVID-19 and a dose of 5 milliliter of a syrup containing 430 mg Calcium fructoborate solution prepared by Arnica daru Danesh Adrin Co. prescribed daily by oral route from the first day of admission to completion of ten days.

Category

Treatment - Drugs

2

Description

Control group: Standard therapeutic regimen for COVID-19 and a dose of placebo as syrup prepared by Arnica daru Danesh Adrin Co. with the same color, odour, taste and volume of the the syrup prescribed for the intervention group for daily oral use till 10 days, for patients in control group.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Bualisina Hospital

Full name of responsible person

Behzad Bijani

Street address

Bualisina hospital, Buali St.

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Postal code

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Phone

+98 28 3333 2930

Email

dr.bijani@gmail.com

2

Recruitment center

Name of recruitment center

Velayat Hospital

Full name of responsible person

Amin Karampour

Street address

Velayat hospital, Taavon Sq, 22 bahman Blvd, Elaheeyeh line, Minoodar town

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+98 28 3379 0620

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amin.karampour@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arnica darou danesh adrin
Full name of responsible person
Mohsen Hattami
Street address
No 1, Andishnandan Blvd, Shaheed Babayee Blvd, Barajin
City
قزوین
Province
Qazvin
Postal code
3471991984
Phone
+98 28 3335 4808
Email
mohsen_hattami@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Arnica darou danesh adrin
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
Industry

Person responsible for general inquiries

Contact
Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person
Behzad Bijani
Position
Assiciate Professor
Latest degree
Specialist
Other areas of specialty/work
Infectious diseases
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Specialist
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Person responsible for updating data

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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
All data, after the individuals are unidentified, can be shared
When the data will become available and for how long
Six months after publishing the results
To whom data/document is available
Academic researchers
Under which criteria data/document could be used
Scientific purposes
From where data/document is obtainable
Website of the Research Committee of Qazvin University of Medical Sciences
What processes are involved for a request to access data/document
Clear request on the site to access the data by the individual and then review the request by the research assistant within 2 weeks and then allow access to the data.
Comments