Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

Effects of High-dose Vitamin C on Treatment, Clinical Symptoms and Laboratory Signs of Iranian COVID-19 Patients: A Double Blind Randomized Clinical Trial

Protocol summary

Study aim
We aimed to assess the effect of high dose vitamin C on clinical improvement and inflammatory indices in moderate to severe COVID-19 patients.

Design
Randomized double blind clinical trial on two arms containing control and treatment group

Settings and conduct
After selecting eligible patients in Dr. Shariati teaching hospital, pharmacist will allocate each patient to one study group by table of randomization and prepare the serum content. investigator, physician and healthcare provider are blinded. biochemical tests, inflammatory indices and respiratory support will be assessed based on defined schedule. At the end of the study results will be presented to analyzer in two blinded groups.

Participants/Inclusion and exclusion criteria
Confirmed moderate to severe COVID-19, age more than 18 years and consent for participation in the study, negative history for nephrolithiasis, chronic kidney disease (stage 4) and hemodialysis, pregnancy and breastfeeding will included in this study.

Intervention groups
Treatment group will receive 12g Vitamin C in dextrose5% to total volume of 200 ml for 4 days and placebo group will receive distilled water in dextrose5% to total volume of 200 ml for 4 days.

Main outcome variables
Time to clinical improvement (TTIC), change in Sequential Organ Failure Assessment (SOFA) score, National Early Warning Score (NEWS) 2, Ordinal scale for clinical improvement, Length of hospital stays, inflammatory indices, and mortality

General information

Reason for update
Revision of inclusion and exclusion criteria and outcomes

Acronym

IRCT registration information
IRCT registration number: **IRCT20190917044805N2**
Registration date: **2020-03-31, 1399/01/12**
Registration timing: **prospective**

Last update: **2021-07-10, 1400/04/19**
Update count: **1**

Registration date
2020-03-31, 1399/01/12

Registrant information

Name
Kourosh Sadeghi

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-04-03, 1399/01/15

Expected recruitment end date
2020-10-06, 1399/07/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Effects of High-dose Vitamin C on Treatment, Clinical Symptoms and Laboratory Signs of Iranian COVID-19 Patients: A Double Blind Randomized Clinical Trial

Public title
Effects of High-dose Vitamin C on COVID-19
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Older than 18 years old admission with moderate to severe COVID-19 based on WHO definition Illness of any duration, and at least one of the following: Radiographic infiltrates by imaging (chest x-ray, CT scan, etc.), or Clinical assessment AND respiratory rate > 30 breaths/min; or severe respiratory distress; or SpO2 < 90% on room air. Willing and be able to provide written informed consent prior to performing study procedures
Exclusion criteria:
Participation in any other clinical trial of an experimental treatment for COVID-19 Critical ill patients that need invasive mechanical ventilation Stage 4 severe chronic kidney disease or requiring dialysis (i.e. eGFR < 30) Patients with past medical history of kidney stone Pregnancy or breastfeeding Documented diagnosis of cancer History of G6PD deficiency and interstitial lung disease More than 1 gram/day intake of vitamin C supplement in last 7 days
Age
From **18 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
The method of randomization is based on block randomization using random 4 blocks. Table of patients number and block Randomization codes will be created by Online randomization web page and will be presented to pharmacist in-charged for serum content preparation. investigator informs patient inclusion number and serum ingredient will be determined by pharmacist based on randomization table.
Blinding (investigator's opinion)
Double blinded
Blinding description
this study will be conducted as a double blind process. patients, investigator, health care workers including nurses and physicians, statistical analyzer will be blinded, by preparing serum content by pharmacist and allocating a code to each serum. pharmacist is the only one who knows the content and has no role in data gathering and result interpretation.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Vice-Chancellor In Research Affairs- Tehran University of Medical Science
Street address
Vice Chancellor for Research and Technology, Sixth Floor, Qods Ave., Keshavarz Blvd.
City
Tehran
Province
Tehran
Postal code
۱۴۱۷۴۱۴۴۱۸
Approval date
2020-03-27, 1399/01/08
Ethics committee reference number
IR.TUMS.VCR.REC.1399.056

Health conditions studied

1

Description of health condition studied
COVID-19
ICD-10 code
U07.1
ICD-10 code description
COVID-19 confirmed by laboratory testing

Primary outcomes

1

Description
Time to clinical improvement (TTIC)
Timepoint
day 0, 5, at discharge
Method of measurement
assessing respiratory rate, blood oxygen saturation, fever

2

Description
Change in Sequential Organ Failure Assessment (SOFA) score

Timepoint
day 0, 3, and 5
Method of measurement
SOFA scoring system

Secondary outcomes

1

Description
National Early Warning Score (NEWS) 2
Timepoint
On day 0, 3, and 5
Method of measurement
NEWS 2 scoring system

2

Description
Ordinal scale for clinical improvement
Timepoint
On day 0, 3, and 5
Method of measurement
WHO scoring system

3

Description
Hospital Length of Stay
Timepoint
Days after receiving infusion
Method of measurement
days

4

Description
The change of inflammatory markers
Timepoint
On day 0, 3, and 5
Method of measurement
C-reactive protein, Neutrophil-lymphocyte ratio, Ferritin

5

Description
Mortality
Timepoint
During 30 days of receiving infusion
Method of measurement
Number of subjects

Intervention groups

1

Description
Intervention group: this group adjunct to standard treatment will receive intravenous infusion of 12 grams of vitamin C in Dextrose 5% serum to the total volume of 200 ml over 24 hours for 4 days
Category
Treatment - Drugs

2

Description
Control group: infusion of serum containing 120 ml distilled water in Dextrose 5% serum to the total volume of 200 ml over 24 hours for 4 days beside receiving standard treatment.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Dr. Shariati hospital
Full name of responsible person
Kourosh Sadeghi
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Dr Shariati Educational and Research Center, Jalal Al Ahmad Road, North Kargar Ave., Tehran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Kourosh Sadeghi
Position
Assistant Professor
Latest degree
Specialist
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Not applicable
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
data for primary outcomes can be available after requesting scientific responsible person.
When the data will become available and for how long
starting 6 months after publication
To whom data/document is available
this only available for people working in academic institutions

Under which criteria data/document could be used

there is no limitation

From where data/document is obtainable

documents are available by scientific responsible person by email kourosh.sadeghi@gmail.com

What processes are involved for a request to access data/document

documents are available after assessing the aim and identity of requesting person

Comments