

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 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		one who knows the content and has no role in data gathering and result interpretation.	
Public title	Effects of High-dose Vitamin C on COVID-19	Placebo	Used
Purpose	Treatment	Assignment	Parallel
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	Other design features	
Age	From 18 years old	Secondary Ids	empty
Gender	Both	Ethics committees	
Phase	2-3	1	
Groups that have been masked	- Participant - Care provider - Investigator - Outcome assessor - Data analyser	Ethics committee	
Sample size	Target sample size: 60	Name of ethics committee	Vice-Chancellor In Research Affairs- Tehran University of Medical Science
Randomization (investigator's opinion)	Randomized	Street address	Vice Chancellor for Research and Technology, Sixth Floor, Qods Ave., Keshavarz Blvd.
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.	City	Tehran
Blinding (investigator's opinion)	Double blinded	Province	Tehran
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	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**

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Ali Sahraian

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Vice Chancellor for Research and Technology, Sixth Floor, Qods Ave., Keshavarz Blvd.

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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

Other areas of specialty/work

Medical Pharmacy

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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