Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Evaluation of the effect of high-dose vitamin C in the treatment of patients with COVID-19 admitted to the critical care ward

Protocol summary

Study aim
The aim of this study was to evaluate the effect of high dose intravenous vitamin C in COVID-19 patients admitted to the intensive care unit.

Design
Clinical trial with control group, with parallel, non-blind, randomized, phase 2 groups on 200 patients. Excel software rand function will be used for randomization.

Settings and conduct
Patients are randomly divided into intervention and control groups according to the treatment protocol of the Ministry of Health and in the intervention group, despite treatment with standard protocol, vitamin C is also prescribed.This treatment will be every 12 hours and 4 grams per day.

Participants/Inclusion and exclusion criteria
Inclusion criteria: adults (18 years and older); respiratory failure index (RIF) (arterial oxygen stress (or pressure)/ fraction-inspired oxygen) <300 mm Hg; treated in ICU. Exclusion criteria: patients with a history of vitamin C allergy; patients with asthma due to cardiopulmonary edema; pregnant or lactating women; patients whose survival time is less than 24 hours; patients with a previous history of end-stage lung disease, end-stage malignant tumor, G-6-PD deficiency, diabetic ketoacidosis, active kidney stone disease, and severe kidney disease; patients who have already enrolled in another clinical trial; patients with a known history of kidney disease, chronic renal failure, or acute renal failure during hospitalization will be excluded from the study.

Intervention groups
Intervention group: COVID-19 patients will receive standard drugs of the national protocol and vitamin C by injection. The control group includes patients who receive standard drugs of the national protocol and vitamin C placebo.

Main outcome variables
Oxygen saturation; respiration rate; length of hospital stay; mortality rate

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210714051891N1**
Registration date: **2021-09-29, 1400/07/07**
Registration timing: **prospective**

Last update: **2021-09-29, 1400/07/07**
Update count: **0**

Registration date
2021-09-29, 1400/07/07

Registrant information

Name
Moloud Balafar

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 41 3335 2078

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-10-07, 1400/07/15

Expected recruitment end date
2021-12-06, 1400/09/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Evaluation of the effect of high-dose vitamin C in the treatment of patients with COVID-19 admitted to the critical care ward

Public title
The effect of vitamin C in the treatment of patients with COVID-19

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Respiratory failure index (RIF) Treated in the ICU

Exclusion criteria:
Patients with a history of vitamin C allergy. Patients with asthma due to cardiopulmonary edema Pregnant or lactating women Patients with a survival time of less than 24 hours Patients with a history of end-stage lung disease, end-stage malignant tumor, G-6-PD deficiency, diabetic ketoacidosis, active kidney stone disease, and severe kidney disease Patients who have already enrolled in another clinical trial Patients with a known history of kidney disease, chronic renal failure, or acute renal failure during hospitalization

Age
From **18 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **200**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization; randomization unit: individual; randomization tool: using EXCEL software in two groups randomly

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Tabriz University of Medical Sciences

Street address
Research Vice-Chancellor, Tabriz University of Medical Sciences, Golgasht Street

City
Tabriz

Province
East Azarbaijan

Postal code
5166614766

Approval date
2021-08-30, 1400/06/08

Ethics committee reference number
IR.TBZMED.REC.1400.519

Health conditions studied

1

Description of health condition studied
COVID-19 patients

ICD-10 code
U07.1

ICD-10 code description
COVID-19, virus identified

Primary outcomes

1

Description
The amount of lung involvement in a CT scan

Timepoint
Every 12 hours, Up to 10 days

Method of measurement
According to the radiologist, the appearance of lung involvement and the percentage of lung involvement are measured.

Secondary outcomes

1

Description
Oxygen saturation

Timepoint
Every 12 hours, Up to 10 days

Method of measurement
Observations and clinical examinations

2

Description
Respiratory rate

Timepoint
Every 12 hours, Up to 10 days

Method of measurement
Observations and clinical examinations

3

Description

Duration of hospitalization

Timepoint

Daily since hospitalization time

Method of measurement

Based on patient records

4

Description

Mortality rate

Timepoint

Daily

Method of measurement

Census

Intervention groups

1

Description

Intervention group: Vitamin C is made by Osweh Pharmaceutical Company, will be administered 4 grams by injection every 12 hours for 10 days.

Category

Treatment - Drugs

2

Description

Control group: They will not receive any intervention

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Moloud Balafar

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Moloud Balafar

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

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inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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