Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

Interventional study of intravenous vitamin C in definitive patients with covid 19 and its effect on changes in lung CT scan and clinical and laboratory symptoms of patients

Protocol summary

Study aim

Determination of the effect of intravenous vitamin C in patients with definitive covid 19 and its effect on changes in lung CT scan and clinical and laboratory symptoms of patients

Design

Clinical trial with control group, with parallel, bilateral blind, randomized group on 50 patients

Settings and conduct

This study is being performed at Labbafi Nejad Hospital in Tehran on patients with covid 19 pneumonia. Eligible patients enter the study and are divided into two groups after obtaining consent with antibiotic regimen and similar underlying disease. High-dose intravenous vitamin C treatment is given for five days. After five days, the variables will be evaluated and the two groups will be compared.

Participants/Inclusion and exclusion criteria

Patients with covid 19 have been admitted to study conditions. Inclusion criteria: Respiratory Rate> 30, Oxygen Saturation <93%, or lung Infiltration> 50% in lung CT scan Exclusion criteria: Vitamin C allergy, Dyspnea due to cardiac pulmonary edema, Pregnant or breastfeeding women, Chronic kidney disease, Diabetic ketoacidosis, Kidney stones

Intervention groups

This study examines patients with covid 19 who are hospitalized. Patients who are eligible to study are selected first. Then, after obtaining patient consent, treatment with intravenous vitamin C will begin. The dose for this drug supplement is 2 grams every 6 hours and the duration of treatment is 5 days. Attempts are made to treat patients on a similar medication regimen and to have similar variables in terms of age and underlying disease, to minimize the distorting effect of these variables.

Main outcome variables

High doses of intravenous vitamin C affect oxygen oxygenation, respiration rate, pulmonary involvement in CT scan, length of hospital stay, mortality rate, serum CRP level, lymphopenia rate of patients with definitive covid 19.

General information

Reason for update

Acronym

VCACS

IRCT registration information

IRCT registration number: **IRCT20200516047468N1**
Registration date: **2020-05-19, 1399/02/30**
Registration timing: **retrospective**

Last update: **2020-05-19, 1399/02/30**
Update count: **0**

Registration date

2020-05-19, 1399/02/30

Registrant information

Name

Hamideh Moradi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2243 1919

Email address

hamidehmoradi05@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-08, 1399/01/20

Expected recruitment end date

2020-05-09, 1399/02/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Interventional study of intravenous vitamin C in definitive patients with covid 19 and its effect on changes in lung CT scan and clinical and laboratory symptoms of patients

Public title

Investigation of the effect of intravenous vitamin C on definite patients with coronavirus pneumonia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients who have a positive corona pcr test. Patients over 18 years of age. Oxygen saturation should be below 93%. The patient's respiratory rate should be more than 30 per minute. Lung involvement in chest or CT scans of the lungs is more than 50 percent.

Exclusion criteria:

Allergy to vitamin C The patient's shortness of breath may be due to cardiac pulmonary edema Be pregnant or breastfeeding Have chronic kidney disease Be in diabetic ketoacidosis Have kidney stones

Age

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple individual randomization is used. Patients eligible to enter the study are randomly selected from a table of numbers and divided into control and intervention groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, patients with covid 19 who have the conditions to enter the study are first explained about the possible effects of vitamin C on their disease and consent is obtained to start the drug. The intravenous vitamin C is then injected into a group and the placebo is injected into the control group. Laboratory staff and radiologists who report CT scans of patients are unaware of the names of patients in the control group.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shahid Beheshti University of Medical Sciences

Street address

Third Floor, Faculty of Medicine, Next to Taleghani Hospital, Evin, Shahid Chamran Highway

City

Tehran

Province

Tehran

Postal code

1985717434

Approval date

2020-05-04, 1399/02/15

Ethics committee reference number

IR.SBMU.RETECH.REC.1399.067

Health conditions studied

1

Description of health condition studied

COVID 19 PNEUMONIA

ICD-10 code

U07.1

ICD-10 code description

This code assigned to a disease diagnosis of COVID-19 confirmed by laboratory testing.

Primary outcomes

1

Description

The amount of lung involvement in a CT scan: According to the radiologist, the appearance of lung involvement and the percentage of lung involvement are measured

Timepoint

Five days after receiving vitamin C intravenously

Method of measurement

According to the radiologist, the appearance of lung involvement and the extent of lung involvement are scoring.

Secondary outcomes

1

Description
Oxygen saturation rate of patients
Timepoint
Five days after receiving vitamin C intravenously
Method of measurement
Using an pulse oxymeter

2

Description
Respiratory rate of patients
Timepoint
Five days after receiving vitamin C intravenously
Method of measurement
Examination by a doctor

3

Description
Serum CRP level
Timepoint
Five days after receiving vitamin C intravenously
Method of measurement
Report by Laboratory

4

Description
lymphopenia rate
Timepoint
Five days after receiving vitamin C intravenously
Method of measurement
Report by Laboratory

5

Description
mortality rate
Timepoint
At the end of the patient's hospitalization
Method of measurement
report by doctor

6

Description
Duration of hospitalization
Timepoint
At the end of the patient's hospitalization
Method of measurement
Calculated by a physician

7

Description
Intubation rate
Timepoint
At the end of the study
Method of measurement
Calculated by the analyzer

Intervention groups

1

Description
Intervention group: In this group of patients, intravenous vitamin C is injected at a dose of 2 grams every 6 hours for five days. The manufacturer of this drug is Iran Daroupakhsh Company. Patients in the intervention group, in addition to intravenous vitamin C, are used diets of meropenem, vancomycin, azithromycin, and Kaletra. Interferon beta injections are also used in some critically ill patients.
Category
Treatment - Drugs

2

Description
Control group: In patients of this group, placebo is injected for five days. Patients in the control group, in addition to placebo, used the medicinal diets of meropenem, vancomycin, azithromycin, and Kaletra. Interferon beta injections are also used in some critically ill patients.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Labbafi Nejad Educational and Medical Hospital
Full name of responsible person
Hamideh Moradi Shahr Babak
Street address
9th Boostan St, Pasdaran, Tehran
City
Tehran
Province
Tehran
Postal code
1666663111
Phone
+98 21 23601
Email
hamidehmoradi05@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Afshin Zarghi
Street address
Deputy of Research and Technology, 5th Floor, Headquarters Building 2, Shahid Beheshti University

of Medical Sciences and Health Services, Shahid Abbas Aarabi St, Yemen St, Shahid Chamran Highway

City
Tehran

Province
Tehran

Postal code
1983969411

Phone
+98 21 2243 9780

Email
Mpajouhesh@sbmu.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Hamideh Moradi Shahr Babak

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Infectious diseases

Street address
Unit 3, No. 4, Ebrahimi Alley, Shahid Madani St., Nezam Abad, Tehran

City
Tehran

Province
Tehran

Postal code
1616663914

Phone
+98 34 3411 2418

Email
hamidehmoradi05@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Hamideh Moradi Shahr Babak

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Infectious diseases

Street address
Unit 3, No. 4, Ebrahimi Alley, Shahid Madani St., Nezam Abad, Tehran

City
Tehran

Province
Tehran

Postal code
1616663914

Phone
+98 34 3411 2418

Email
hamidehmoradi05@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Hamideh Moradi Shahr Babak

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Infectious diseases

Street address
Unit 3, No. 4, Ebrahimi Alley, Shahid Madani St., Nezam Abad, Tehran

City
Tehran

Province
Tehran

Postal code
1616663914

Phone
+98 34 3411 2418

Email
hamidehmoradi05@gmail.com

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 patient data can be shared after people have not been identified.

When the data will become available and for how long

Start access 3 months after printing the results

To whom data/document is available

Data can be provided to all individuals and institutions.

Under which criteria data/document could be used

Individuals applying for data must have a valid ID card, the purpose of receiving the data must be explained and it must be guaranteed that the data will not be published.

From where data/document is obtainable

To receive data, refer to the office of the Infectious Diseases Department of Labafinejad Hospital in Tehran. Address: Tehran, Pasdaran, 9th Bustan Street

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

After the applicant comes in person with the required documents, the data will be provided to her after three days.

Comments