Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 May 2026

Assessment of intravenous of vitamin C therapeutic effects on laboratory findings in covid-19 patients

Protocol summary

Study aim

Determining and comparing the therapeutic effects of intravenous vitamin C injection on laboratory findings in covid-19 patients

Design

A clinical trial with a control placebo group; parallel groups; single-blind; phase 3; performed on 90 patients; using Random Allocation Software.

Settings and conduct

The study is a one-sided blind clinical intervention .Initially, 90 patients with covid-19 who were admitted to Taleghani hospital wards were divided into two groups of 45 receiving standard treatment with intravenous vitamin C (intervention group) and receiving only standard treatment (control group).The intervention includes injection of vitamin C in amount of 1.5 gr for each patient in the intervention group by intravenous infusion ,using normal saline 500 cc in 4 hours, at the moment of entering the ward. Both study groups will receive all standard procedures and treatment, equally, but do not know which placebo to inject and which drug.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Adults (age 18 years or older); SPO2<92%; Being treated in the ward; Positive PCR test; Involvement of Chest-CT-Scan. Exclusion criteria: Patients with a history of allergy to vitamin C; Patients with dyspnea caused by cardiogenic pulmonary edema; Pregnant and Lactating women; Patients with a previous history of end-stage pulmonary disease, end-stage malignant tumor, diabetic ketoacidosis, severe kidney disease; Active kidney stone disease

Intervention groups

The intervention includes injection of vitamin C in amount of 1.5 gr for each patient in the intervention group by intravenous infusion ,using normal saline 500 cc in 4 hours, at the moment of entering the ward and for control group ,a placebo with the above specification is injected.

Main outcome variables

WBC ,CRP ,ESR , AST ,ALT ,ALK.P, PT ,PTT ,INR ,LDH ,Ferritin , D-dimer , duration of hospitalization ,death

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220228054146N1**
Registration date: **2022-03-02, 1400/12/11**
Registration timing: **retrospective**

Last update: **2022-03-02, 1400/12/11**
Update count: **0**

Registration date

2022-03-02, 1400/12/11

Registrant information

Name

Reza Malek

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 44 3224 8760

Email address

drreza881370@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-03-21, 1400/01/01

Expected recruitment end date

2021-12-22, 1400/10/01

Actual recruitment start date

2021-03-21, 1400/01/01

Actual recruitment end date

2021-09-22, 1400/06/31

Trial completion date
2021-09-22, 1400/06/31

Scientific title
Assessment of intravenous of vitamin C therapeutic effects on laboratory findings in covid-19 patients

Public title
Effects of vitamin C on covid-19 patients

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Adults (age 18 years or older) SPO2<92% Being treated in the ward Positive PCR test Involvement of Chest-CT-Scan

Exclusion criteria:
Patients with a history of allergy to vitamin C Patients with dyspnea caused by cardiogenic pulmonary edema Pregnant women Lactating women Patients with a previous history of end-stage pulmonary disease, end-stage malignant tumor, diabetic ketoacidosis, severe kidney Active kidney stone disease

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant

Sample size
Target sample size: **90**
Actual sample size reached: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients are divided into two groups of vitamin C treatment (intervention group) and the control group using Block Randomization Method. Initially, 6 blocks are prepared with the AAABBB combination and all possible modes of this combination are listed. A specific code is then assigned to each combination. Then, according to the sample size and the volume of the blocks, 14 blocks are selected ,using randomization method .All this process is done, using Random Allocation Software under the supervision of an epidemiologist.

Blinding (investigator's opinion)
Single blinded

Blinding description
All participants in this study are divided into two groups, receiving vitamin C (intervention group) and the control group, but expect for health staff, no patient knows that the placebo was injected or vitamin C. So only patients in this study are blind.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

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

Street address
Resalet Blvd ,Urganse Alley, Urmia University of Medical Sciences

City
Urmia

Province
West Azarbaijan

Postal code
5714783734

Approval date
2021-03-10, 1399/12/20

Ethics committee reference number
IR.UMSU.REC.1400.009

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
White Blood Cell including neutrophil and lymphocyte

Timepoint
Before the intervention and 5 days after

Method of measurement
Measure with blood test and scale with X1000/mm3

2

Description
Inflammatory factor(Erythrocyte Sedimentation Rate)/ESR

Timepoint
Before the intervention and 5 days after

Method of measurement
Measure with blood test and scale with mm/h

3

Description
Inflammatory factor (C-Reactive Protein)/CRP

Timepoint
Before the intervention and 5 days after
Method of measurement
Measure with blood test and scale with Diagnostic Kit Unite /liter

4

Description
Alkaline Phosphatase(Enzyme in liver and bones)/ALK-P
Timepoint
Before the intervention and 5 days after
Method of measurement
Measure with blood test and scale with Diagnostic Kit Unite /liter

5

Description
Aspartate aminotransferase(Liver enzyme)/AST
Timepoint
Before the intervention and 5 days after
Method of measurement
Measure with blood test and scale with Diagnostic Kit Unite /liter

6

Description
Alanine aminotransferase(Liver enzyme)/ALT
Timepoint
Before the intervention and 5 days after
Method of measurement
Measure with blood test and scale with Diagnostic Kit Unite /liter

7

Description
Lactate dehydrogenase(Enzyme in heart and Red blood cell)/LDH
Timepoint
Before the intervention and 5 days after
Method of measurement
Measure with blood test and scale with Diagnostic Kit Unite /liter

8

Description
Blood coagulation factor(D-dimer)
Timepoint
Before the intervention and 5 days after
Method of measurement
Measure with blood test and scale with Diagnostic Kit Unite /liter

9

Description
Blood coagulation factor(Prothrombin Time)/PT
Timepoint
Before the intervention and 5 days after
Method of measurement
Measure with blood test and scale with Diagnostic Kit Unite /liter

10

Description
Blood coagulation factor(Partial Thromboplastin Time)/PTT
Timepoint
Before the intervention and 5 days after
Method of measurement
Measure with blood test and scale with Diagnostic Kit Unite /liter

11

Description
Blood coagulation factor(International Normalized Ratio)/INR
Timepoint
Before the intervention and 5 days after
Method of measurement
Measure with blood test and scale with Diagnostic Kit Unite /liter

12

Description
Inflammatory factor(Ferritin)
Timepoint
Before the intervention and 5 days after
Method of measurement
Measure with blood test and scale with Diagnostic Kit Unite /liter

Secondary outcomes

1

Description
Duration of hospitalization
Timepoint
Day of arrival until discharge from the hospital
Method of measurement
Patient record

2

Description
Death
Timepoint
Day of arrival until discharge from the hospital or death
Method of measurement
Patient record

Intervention groups

1

Description
Intervention group: Injection of vitamin C (Caspian

Company) in amount of 1.5 gr for each patient in the intervention group is performed as an intravenous infusion using normal saline serum(500 cc) in 4 hours ,at the moment of entering the ward.

Category

Treatment - Drugs

2

Description

Control group: Injection of placebo in amount of 1.5 gr for each patient in the control group is performed as an intravenous infusion using normal saline serum(500 cc) in 4 hours ,at the moment of entering the ward.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Taleghani hospital

Full name of responsible person

Dr.Rahim Nejadrahim

Street address

Kashani street , Taleghani hospital

City

Urmia

Province

West Azarbaijan

Postal code

5713613481

Phone

+98 914 141 1057

Email

Nejadrahim@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Dr. Saber Golizadeh

Street address

Resalet Blvd ,Urganse Alley, Urmia University of Medical Sciences

City

Urmia

Province

West Azarbaijan

Postal code

5714783734

Phone

+98 44 3223 1930

Fax

+98 44 3224 0642

Email

GolizadeSaber12@yahoo.com

Grant name

Grant code / Reference number

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

No

Title of funding source

Reza Malek

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Reza Malek

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Pathology

Street address

Jahad Blvd, Rahnamayi Blvd, Modiriat street, Emdad Alley, Gavam Apartment, First Floo

City

Urmia

Province

West Azarbaijan

Postal code

5713613481

Phone

+98 44 3224 8760

Email

drreza881370@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Reza Malek

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Pathology

Street address

Jahad Blvd, Rahnamayi Blvd, Modiriat street, Emdad Alley, Gavam Apartment, First Floo

City
Urmia

Province
West Azarbaijan

Postal code
5713613481

Phone
+98 44 3224 8760

Email
Drreza881370@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Oroumia University of Medical Sciences

Full name of responsible person
Reza Malek

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Pathology

Street address
Jahad Blvd, Rahnamayi Blvd, Modiriat street, Emdad Alley, Gavam Apartment, First floo

City
Urmia

Province
West Azarbaijan

Postal code
5713613481

Phone
+98 44 3224 8760

Email
drreza881370@yahoo.com

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
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available