

# 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

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

#### 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

#### 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**

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**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

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+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

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**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**

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**Other areas of specialty/work**

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**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**

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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**

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