# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

30 May 2026

## Evaluation of the effectiveness of vitamin compared to routine medication treatment on the improvement process of patients with COVID-19

### Protocol summary

**Study aim**
Determining the effectiveness of vitamin C on the improvement process of patients with COVID-19 in Abadan University of Medical Sciences

**Design**
A parallel randomized double blind clinical trial with intervention and placebo group

**Settings and conduct**
This study will be done in hospitals affiliated to abadan university of medical sciences. 400 Covid-90 patients with inclusion criteria will be assigned to intervention (Vitamin C) and placebo group. The randomization method is block randomization. In this study patients and researchers will be blinded

**Participants/Inclusion and exclusion criteria**
Inclusion criteria: Patients who are diagnosed as Covid-19 patients by positive PCR test or by CT Scan Exclusion criteria: Pregnant or breast feeding women, Patients with a kidney stone, Patients with diabetes, Patients under 18 years of age, Chronic renal failure, Patient with urinary tract infection

**Intervention groups**
Intervention Group: Patients with Covid-19 that will be Recipient of standard national protocol drugs + Vitamin C 1000mg daily Control Group: Patients with Covid-19 that will be Recipient of standard national protocol drugs + placebo of Vitamin C

**Main outcome variables**
Recovery within 10 days of starting the drug. Recovery means: (no fever, no shortness of breath, no cough or improved, no fatigue or improved) for 24 hours.

### General information

**Reason for update**
Edit date of recruitment and outcomes

**Acronym**
-

**IRCT registration information**
IRCT registration number: **IRCT20200324046850N5**
Registration date: **2020-04-04, 1399/01/16**
Registration timing: **prospective**

Last update: **2020-10-17, 1399/07/26**
Update count: **1**

**Registration date**
2020-04-04, 1399/01/16

**Registrant information**

**Name**
Sara Mobarak

**Name of organization / entity**

**Country**
Iran (Islamic Republic of)

**Phone**
+98 61 5326 7800

**Email address**
s.mobarak@abadanums.ac.ir

**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2020-10-17, 1399/07/26

**Expected recruitment end date**
2020-12-16, 1399/09/26

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**
Evaluation of the effectiveness of vitamin compared to

routine medication treatment on the improvement process of patients with COVID-19

**Public title**
Effectiveness of vitamin C on the improvement process of patients with COVID-19
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
COVID-19 patients that have positive PCR test of nasopharyngeal sample or have positive CT Scan
**Exclusion criteria:**
Pregnant or breast feeding women Patients with kidney stone Patients with diabetes Patients under 18 years of age Chronic renal failure Patient with urinary tract infection
**Age**
From **18 years** old
**Gender**
Both

**Phase**
2
**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor

**Sample size**
Target sample size: **400**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
Randomization method is block randomization and block size of 4. Randomization sequence and concealment codes will de created by www.sealedenvelope.com website.
**Blinding (investigator's opinion)**
Double blinded
**Blinding description**
Placebo will be produced with a color and taste similar to Vitamin C by Pharmacy school of Jundishapur University.
**Placebo**
Used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Abadan faculty of medical sciences
**Street address**
-
**City**
Abadan
**Province**
Khouzestan
**Postal code**
06313833177
**Approval date**
2020-03-17, 1398/12/27
**Ethics committee reference number**
IR.ABADANUMS.REC.1398.119

## Health conditions studied

### 1

**Description of health condition studied**
Covid-19
**ICD-10 code**
U07.1
**ICD-10 code description**
Covid-19

## Primary outcomes

### 1

**Description**
Recovery within 10 days of starting the drug. Recovery means: (no fever, no shortness of breath, no cough or improved, no fatigue or improved) for 24 hours.
**Timepoint**
Daily
**Method of measurement**
Clinical observation and examination

## Secondary outcomes

### 1

**Description**
The change of inflammatory markers
**Timepoint**
Admission and discharge day
**Method of measurement**
C-reactive protein, neutrophil-lymphocyte ratio

### 2

**Description**
Rate of survival
**Timepoint**
Daily
**Method of measurement**
census report

### 3

**Description**
Days admitted in hospital
**Timepoint**
Daily since hospitalization time
**Method of measurement**

Based on patient's file

**4**

**Description**
Days intubated/under ventilator
**Timepoint**
Daily
**Method of measurement**
observation

**5**

**Description**
Days admitted in ICU
**Timepoint**
Daily
**Method of measurement**
Based on patient's file

**6**

**Description**
Time to clinical improvement (TTIC) of NEWS2 (National Early Warning Score 2) of 0 maintained for 24 hours
**Timepoint**
Day of admission, fifth and discharge
**Method of measurement**
NEWS2 (National Early Warning Score 2) questionnaire

## Intervention groups

**1**

**Description**
Control group: Standard Protocol Drugs + placebo (in terms of appearance and color similar to vitamin C) every 12 hours for 5 days
**Category**
Treatment - Drugs

**2**

**Description**
Intervention group: Standard Protocol Drugs + Vitamin C 500mg every 12 hours for 5 days
**Category**
Treatment - Drugs

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Abadan Taleghani Hospital
**Full name of responsible person**
سارا مبارک
**Street address**
-
**City**
Abadan
**Province**
Khouzestan
**Postal code**
6313833177
**Phone**
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**Email**
s.mobarak@abadanums.ac.ir

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Abadan University of Medical Sciences
**Full name of responsible person**
Sara Mobarak
**Street address**
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**City**
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s.mobarak@abadanums.ac.ir
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Abadan 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**
Abadan University of Medical Sciences
**Full name of responsible person**
Sara Mobarak
**Position**
Associate professor
**Latest degree**
Specialist
**Other areas of specialty/work**
Infectious diseases

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## Person responsible for scientific inquiries

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## Person responsible for updating data

**Contact**
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## 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 data can be shared after the participants in the study are unrecognizable.
**When the data will become available and for how long**
The data access period after printing the article
**To whom data/document is available**
The data in this study will be available to researchers working at academic and scientific institutions, as well as the Food and Drug Administration.
**Under which criteria data/document could be used**
Any analysis can be done with the consent of the main researcher.
**From where data/document is obtainable**
s.mobarak@abadanums.ac.ir
**What processes are involved for a request to access data/document**
The researcher or pharmaceutical company can send their request to the academic email after sending the documents to confirm their original identity.The project manager will then provide the requested information to the researcher or pharmaceutical company after ensuring the accuracy of the submitted documents after a period of one week.
**Comments**