

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-19 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 be 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

Khuzestan

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

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Postal code

6313833177

Phone

+98 61 5326 7800

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

-

City

Abadan

Province

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Postal code

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Phone

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Email

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

Street address

-

City

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Fax**Email**

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Person responsible for scientific 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 updating data**Contact****Name of organization / entity**

Abadan University of Medical Sciences

Full name of responsible person

Sara Mobarak

Position

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Fax**Email**

S.mobarak@abadanums.ac.ir

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