

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Sep 2021

### Comparison of vitamin D3 and N-acetylcysteine prescription in COVID19 patients and their effect on recovery process

#### Protocol summary

##### Study aim

Comparison of the administration of vitamin D3 and N acetylcysteine tablets in COVID-19 patients and their effect on recovery

##### Design

This study will be conducted on randomized, double-blind, phase 3 clinical trials in 100 patients. Randomization method is block randomization and block size was 8 and 4.

##### Settings and conduct

This randomized, double-blind clinical trial is being conducted at Ayatollah Taleghani Hospital in Abadan. The study was performed on 100 patients with COVID-19 who were admitted to the infectious disease ward of Ayatollah Taleghani Hospital. A written consent was obtained for this study. In this study participants, researchers and outcome assessment are blind.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: COVID-19 patients that have positive PCR test of nasopharyngeal sample or have positive CT Scan for COVID-19. Exclusion criteria: Pregnant or breast feeding women, Patients under 18 years of age, Any life-threatening factor

##### Intervention groups

Note: standard country protocol drugs (lopinavir (50 mg) -ritonavir (200 mg) 2 tablets every 12 hours + hydroxychloroquine (200 mg) two tablets one dose). The first group: Patients receiving standard country protocol drugs with vitamin D3 ampoules of 50,000 units once a week and N-acetylcysteine placebo tablets every 12 hours The second group: Patients receiving standard country protocol drugs with 600mg N-acetylcysteine tablet every 12 hours and vitamin D3 placebo once a week The third group: Patients receiving standard country protocol drugs with 600mg N-acetylcysteine tablets every 12 hours and 500,000 units of vitamin D3 once a week The fourth group: Patients receiving standard country protocol drugs with placebo vitamin D3 once a week and placebo tablets N-acetylcysteine every

12 hours

##### Main outcome variables

Time to clinical improvement defined as start of taking medication time to Discharge Time.

#### General information

##### Reason for update

Update patient history and edit data list editing

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200324046850N1**

Registration date: **2020-03-29, 1399/01/10**

Registration timing: **prospective**

Last update: **2020-06-03, 1399/03/14**

Update count: **1**

##### Registration date

2020-03-29, 1399/01/10

##### 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

2020-06-06, 1399/03/17

##### Expected recruitment end date

2020-07-07, 1399/04/17

##### Actual recruitment start date

empty  
**Actual recruitment end date**  
empty  
**Trial completion date**  
empty

**Scientific title**  
Comparison of vitamin D3 and N-acetylcysteine prescription in COVID19 patients and their effect on recovery process

**Public title**  
Comparison of vitamin D3 and N-acetylcysteine prescription in COVID-19 patients and their effect on recovery process

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
COVID-19 patients that have positive PCR test of nasopharyngeal sample or have positive CT Scan for COVID-19.

**Exclusion criteria:**  
Pregnant or breast feeding women Patients under 18 years of age Any life-threatening factor

**Age**  
From **18 years** old

**Gender**  
Both

**Phase**  
3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

**Sample size**  
Target sample size: **100**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
This study will be a randomized, double-blind, phase 3 clinical trials on 100 patients. Randomization method is block randomization and block size was 8 and 4. Randomization sequence and concealment codes will be created by www.sealedenvelope.com website. Sealed envelopes were used for allocation concealment.

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**  
. In this study participants, researchers,Care provider, Data analyser and outcome assessor are blind. The drugs used were similar in appearance, So patients do not understand which group they are in. Sealed envelopes were used for allocation concealment.

**Placebo**  
Used

**Assignment**  
Factorial

**Other design features**

## Secondary Ids

empty

## Ethics committees

1

### Ethics committee

#### Name of ethics committee

Ethics Committee of Abadan School of Medical Sciences

#### Street address

Abadan School of Medical Sciences,Beginning of the 30 meters Ave, Zolfaghari street, Abadan city.

#### City

Abadan

#### Province

Khuzestan

#### Postal code

631911154 061

### Approval date

2020-03-17, 1398/12/27

### Ethics committee reference number

IR.ABADANUMS.REC.1398.118

## Health conditions studied

1

### Description of health condition studied

Covid-19

### ICD-10 code

U07.1

### ICD-10 code description

Other coronavirus as the cause of diseases classified elsewhere

## Primary outcomes

1

### Description

Time to clinical improvement defined as start of taking medication time to Discharge Time.

### Timepoint

The beginning of the study ,the seventh day, the fourteenth day, the twenty-first day, the twenty-eighth day

### Method of measurement

Medical record

## Secondary outcomes

1

### Description

Complete Blood Count

### Timepoint

The beginning of the study and the time of discharge

### Method of measurement

blood sample

## 2

### **Description**

Venous blood gas

### **Timepoint**

The beginning of the study and the time of discharge

### **Method of measurement**

Blood sample

## 3

### **Description**

C-reactive-protein

### **Timepoint**

The beginning of the study and the time of discharge

### **Method of measurement**

Blood sample

## 4

### **Description**

creatinine

### **Timepoint**

The beginning of the study and the time of discharge

### **Method of measurement**

Blood sample

## 5

### **Description**

Aspartate amino transferase

### **Timepoint**

The beginning of the study and the time of discharge

### **Method of measurement**

Blood sample

## 6

### **Description**

Alanine amino transferase

### **Timepoint**

The beginning of the study and the time of discharge

### **Method of measurement**

Blood sample

## 7

### **Description**

Prothrombin time

### **Timepoint**

The beginning of the study and the time of discharge

### **Method of measurement**

Blood sample

## 8

### **Description**

Partial Thromboplastin time

### **Timepoint**

The beginning of the study and the time of discharge

### **Method of measurement**

Blood sample

## 9

### **Description**

Cough

### **Timepoint**

The beginning of the study ,the seventh day, the fourteenth day, the twenty-first day, the twenty-eighth day

### **Method of measurement**

Clinical observation and examination

## 10

### **Description**

level of consciousness

### **Timepoint**

The beginning of the study ,the seventh day, the fourteenth day, the twenty-first day, the twenty-eighth day

### **Method of measurement**

Using the Glasgow Coma scale

## 11

### **Description**

shortness of breath

### **Timepoint**

The beginning of the study, the seventh day, the fourteenth day, the twenty-first day, the twenty-eighth day

### **Method of measurement**

Clinical observation and examination

## 12

### **Description**

Fatigue

### **Timepoint**

The beginning of the study, the seventh day, the fourteenth day, the twenty-first day, the twenty-eighth day

### **Method of measurement**

Observation and Interview with the patient

## 13

### **Description**

Severe and frequent diarrhea

### **Timepoint**

The beginning of the study, the seventh day, the fourteenth day, the twenty-first day, the twenty-eighth day

### **Method of measurement**

Interview with the patient

## 14

### **Description**

abdominal pain

### **Timepoint**

The beginning of the study, the seventh day, the fourteenth day, the twenty-first day, the twenty-eighth day

### **Method of measurement**

Interview with the patient

## **15**

### **Description**

nausea and vomiting

### **Timepoint**

The beginning of the study, the seventh day, the fourteenth day, the twenty-first day, the twenty-eighth day

### **Method of measurement**

Interview with the patient

## **16**

### **Description**

Olfactory disturbances

### **Timepoint**

The beginning of the study, the seventh day, the fourteenth day, the twenty-first day, the twenty-eighth day

### **Method of measurement**

Interview with the patient

## **17**

### **Description**

Appetite

### **Timepoint**

The beginning of the study, the seventh day, the fourteenth day, the twenty-first day, the twenty-eighth day

### **Method of measurement**

Observation and Interview with the patient

## **18**

### **Description**

Duration of ICU stay

### **Timepoint**

Daily

### **Method of measurement**

Number of days of hospitalization in ICU

## **19**

### **Description**

Adverse events

### **Timepoint**

Time of discharge

### **Method of measurement**

Medical record

## **20**

### **Description**

The patient's condition is based on inpatient or outpatient

### **Timepoint**

The beginning of the study, the seventh day, the fourteenth day, the twenty-first day, the twenty-eighth day

### **Method of measurement**

seven category ordinal scale

## **21**

### **Description**

Mortality rate

### **Timepoint**

Daily

### **Method of measurement**

Medical record

## **22**

### **Description**

Taste disturbances

### **Timepoint**

The beginning of the study, the seventh day, the fourteenth day, the twenty-first day, the twenty-eighth day

### **Method of measurement**

Interview with the patient

## **Intervention groups**

### **1**

#### **Description**

Intervention group 1: Patients receiving standard country protocol drugs (lopinavir (50 mg) -ritonavir (200 mg) 2 tablets every 12 hours until the patient's clinical symptoms improve + hydroxychloroquine (200 mg) two tablets one dose) with vitamin D3 ampoules of 50,000 units once a week and N-acetylcysteine placebo tablets every 12 hours

#### **Category**

Treatment - Drugs

### **2**

#### **Description**

Intervention group 2: Patients receiving standard country protocol drugs (lopinavir (50 mg) -ritonavir (200 mg) 2 tablets every 12 hours until the patient's clinical symptoms improve + hydroxychloroquine (200 mg) two tablets one dose) with 600mg N-acetylcysteine tablet every 12 hours and vitamin D3 placebo once a week

#### **Category**

Treatment - Drugs

### **3**

#### **Description**

Intervention group 3: Patients receiving standard country protocol drugs (lopinavir (50 mg) -ritonavir (200 mg) 2 tablets every 12 hours until the patient's clinical symptoms improve + hydroxychloroquine (200 mg) two tablets one dose) with 600mg N-acetylcysteine tablets every 12 hours and 500,000 units of vitamin D3 once a week

#### **Category**

Treatment - Drugs

## 4

### Description

Intervention group 4: Patients receiving standard country protocol drugs (lopinavir (50 mg) -ritonavir (200 mg) 2 tablets every 12 hours until the patient's clinical symptoms improve + hydroxychloroquine (200 mg) two tablets one dose) with placebo vitamin D3 once a week and placebo tablets N-acetylcysteine every 12 hours

### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Ayatollah Taleghani Hospital

##### Full name of responsible person

Sara Mobarak

##### Street address

Ayatollah Taleghani Hospital. University Blvd. Nurse Square. Abadan city

##### City

Abadan

##### Province

Khouzestan

##### Postal code

631911154

##### 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

Abadan School of Medical Sciences, Beginning of the 30 meters Ave, Zolfaghari street, Abadan city.

##### City

Abadan

##### Province

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##### Postal code

631911154

##### Phone

+98 61 5338 4004

##### Email

s.mobarak@abadanums.ac.ir

##### Grant name

##### Grant code / Reference number

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

No

##### 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

Assistant Professor

##### Latest degree

Specialist

##### Other areas of specialty/work

Infectious diseases

##### Street address

Abadan School of Medical Sciences, Beginning of the 30 meters Ave, Zolfaghari street, Abadan city.

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##### Province

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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

Assistant Professor

##### Latest degree

Specialist

##### Other areas of specialty/work

Infectious diseases

##### Street address

Abadan School of Medical Sciences, Beginning of the 30 meters Ave, Zolfaghari street, Abadan city

##### City

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##### Province

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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**  
Assistant Professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Infectious diseases  
**Street address**  
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**City**  
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**Province**  
Khouzestan  
**Postal code**  
631911154  
**Phone**  
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**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