

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Oct 2020

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

Khouzestan

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

Khouzestan

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.

City

Abadan

Province

Khouzestan

Postal code

6313833177

Phone

+98 61 5338 4004

Email

s.mobarak@abadanums.ac.ir

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

Abadan

Province

Khouzestan

Postal code

631911154

Phone

+98 61 5338 4004

Email

s.mobarak@abadanums.ac.ir

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

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

City

Abadan

Province

Khouzestan

Postal code

631911154

Phone

+98 61 5338 4004

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