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 de 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
creatinne
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

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Abadan

Province
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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.

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Abadan

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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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Person responsible for scientific inquiries

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Name of organization / entity
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Full name of responsible person
Sara Mobarak

Position
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Latest degree
Specialist

Other areas of specialty/work
Infectious diseases

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Person responsible for updating data

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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