Clinical Trial Protocol
Iranian Registry of Clinical Trials

24 Sep 2021

Evaluation of the efficacy and safety of oral N-acetylcysteine in treatment and recovery of patients with COVID-19 who are under treatment with routine protocols

Protocol summary

Study aim
Evaluation of the efficacy and side effects of N-Acetyl Cysteine in the treatment and recovery of patients with COVID-19 in Hazrat Rasool Akram Hospitals: A Randomize Clinical Trial

Design
Clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 on 60 patients. The rand function of the Excel software was used for randomization.

Settings and conduct
Hazrat Rasool akram hospital, covid-19 admission wards randomized clinical trial

Participants/Inclusion and exclusion criteria
inclusion|:hospitalized patients with moderate to severe COVID-19 with stable vital signs exclusion: Patients with unstable vital signs or need for intubation/Patients hospitalized in ICU/ history of hypersensitivity to NAC/pregnancy,lactation and infancy

Intervention groups
Treatment in both control and intervention groups is based on the use of common treatment protocols in patients with covid-19. In the intervention group,oral NAC is added to the routine treatment

Main outcome variables
fever/cough/dyspenia/o2 level/duration of administration/laboratory parameters/ radiologic changes/ICU admission/death

General information

Reason for update

Acronym
NAC

IRCT registration information
IRCT registration number: **IRCT20200623047897N1**
Registration date: **2020-08-16, 1399/05/26**
Registration timing: **registered_while_recruiting**

Last update: **2020-08-16, 1399/05/26**
Update count: **0**

Registration date
2020-08-16, 1399/05/26

Registrant information

Name
Najmolsadat Atefi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 8857 4388

Email address
atefi.ns@iums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-05-21, 1399/03/01

Expected recruitment end date
2020-08-22, 1399/06/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the efficacy and safety of oral N-acetylcysteine in treatment and recovery of patients with COVID-19 who are under treatment with routine protocols

Public title

Efficacy of N-acetylcysteine in patients with COVID-19

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

admitted patients with COVID-19 moderate to severe, stable patients

Exclusion criteria:

unstable and intubated ICU patients pregnancy, breastfeeding infancy allergy and intolerance to NAC unstable vital signs or need for intubation

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, participants were classified by stratified blocked randomization method based on easy sampling method and based on therapeutic regimen (four regimens) and were randomly assigned to one of the groups receiving the intervention (routine treatment regimen+NAC) or the routine treatment regimen alone group. Randomization is done separately within each group. The size of the blocks is 4, with two allocations to the intervention group (A) and two allocations to the routine treatment group (B), which will create 6 different formats as BAAB, ABBA, ABAB, AABB, BABA, BBAA.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of medical scinces

Street address

Hazrat Rasool akram hospital, Mansoori ave, Sattarkhan street

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Approval date

2020-05-10, 1399/02/21

Ethics committee reference number

IR.IUMS.REC.1399.206

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

Time to improve symptoms such as cough, shortness of breath and lethargy

Timepoint

At the beginning of the hospitalization/ two weeks after treatment

Method of measurement

clinical evaluation

2

Description

O2 saturation

Timepoint

At the beginning of the hospitalization/ two weeks after treatment

Method of measurement

clinical evaluation and pulse oximetery

3

Description

Re-hospitalization after discharge

Timepoint

At the beginning of the hospitalization/ two weeks after treatment

Method of measurement

clinical evaluation

4

Description

duration of hospitalization

Timepoint

after discharge

Method of measurement

days

5

Description
Evaluation of laboratory parameters as a series of factors: PCR and LDH, CBC, ESR, CRP Comparison of parameters at the beginning of hospitalization, during hospitalization and at the time of discharge
Timepoint
At the beginning of the hospitalization/ during hospitalization/ at discharge time
Method of measurement
lab data analysis

6

Description
Check for changes in anti-inflammatory parameters (TNF-ALPHA and IL-6 if measuring kits are available)
Timepoint
At the beginning of the hospitalization/ at discharge time
Method of measurement
lab data analysis

7

Description
Investigation of radiological changes at the beginning of hospitalization and during hospitalization if possible
Timepoint
At the beginning of the hospitalization/ during hospitalization
Method of measurement
radiographic changes

8

Description
ICU admission
Timepoint
during hospitalization
Method of measurement
clinical evaluation

9

Description
recovery or death
Timepoint
during hospitalization and after discharge
Method of measurement
clinical evaluation

Secondary outcomes

1

Description
side effects
Timepoint
Time to start the intervention/ during hospitalization, two weeks after interventions
Method of measurement
Clinical, laboratory evaluation

2

Description
need change initial treatment or add new drug to the regimen
Timepoint
during hospitalization
Method of measurement
clinical assessment

Intervention groups

1

Description
Intervention group: hospitalized patients with moderate-sever covid-19 with stable vital signs who receive NAC. In this study, for each specific routine therapeutic regimen (regimen 1: kaletra+ hydroxychloroquine and regimen 2: atazanavir / ritonavir + hydroxychloroquine), two arms of 15 people are defined (15 people in the control group who will receive only the routine regimen and 15 people in the intervention group who will receive 600 mg oral NAC three times a day in addition to the routine regimen).
Category
Treatment - Drugs

2

Description
Control group: hospitalized patients with moderate-sever covid-19 with stable vital signs who do not receive the NAC (N-acetyl cysteine) In this study, for each specific routine therapeutic regimen (regimen 1: kaletra+ hydroxychloroquine and regimen 2: atazanavir / ritonavir + hydroxychloroquine), two arms of 15 people are defined (15 people in the control group who will receive only the routine regimen and 15 people in the intervention group who will receive 600 mg oral NAC three times a day in addition to the routine regimen).
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Hazrate Rasool Akram Hospital
Full name of responsible person
Najmolsadat Atefi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Dr. Seyyed Abbas Motevalian
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran 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
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Position
Associate professor
Latest degree
Specialist
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Person responsible for updating data

Contact
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Niloufar Najar Nobari
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Not applicable