

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 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

Registration timing: **registered_while_recruiting**

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

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

Update count: **0**

Registration date

2020-08-16, 1399/05/26

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.

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

Settings and conduct

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

Recruitment status

Recruitment complete

Funding source

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

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

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

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

Main outcome variables

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

Public title

General information

Reason for update

Acronym

NAC

IRCT registration information

IRCT registration number: **IRCT20200623047897N1**

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

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 sciences

Street address

Hazrat Rasool akram hospital, Mansoori ave, Sattarkhan street

City

Teharn

Province

Tehran

Postal code

۱۴۴۵۶۱۳۱۳۱

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 oximetry

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

Street address

Hazrate Rasool Akram Hospital, Mansoori ave, Sattarkhan street

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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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Web page address
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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
Iran University of Medical Sciences
Full name of responsible person
Najmolsadat Atefi
Position
Associate professor
Latest degree

Specialist
Other areas of specialty/work
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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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