

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Oct 2023

### 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

#### **City**

Tehran

#### **Province**

Tehran

#### **Postal code**

۱۴۴۵۶۱۳۱۳۱

**Phone**  
+98 21 6651 6001  
**Email**  
atefi.ns@iums.ac.ir  
**Web page address**  
<https://hrmc.iums.ac.ir/>

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Iran University of Medical Sciences  
**Full name of responsible person**  
Dr. Seyyed Abbas Motevalian  
**Street address**  
Iran University of Medical Sciences, Shahid Hemmat  
Highway  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1449614535  
**Phone**  
+98 21 8670 2503  
**Fax**  
+98 21 8862 2307  
**Email**  
research-m@iums.ac.ir  
**Web page address**  
[https://vcr.iums.ac.ir](https://vcr.iums.ac.ir/)

#### 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**  
Dermatology  
**Street address**  
Dermatology ward, Hazrate Rasoole Akram Hospital,  
Niayesh St, Satarkhan Av  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
14665354  
**Phone**  
00982164351  
**Email**  
atefi.ns@iums.ac.ir

## Person responsible for scientific 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**  
Dermatology  
**Street address**  
Dermatology ward, Hazrate Rasoole Akram Hospital,  
Niayesh St, Satarkhan Av  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
14665354  
**Phone**  
00982164351  
**Email**  
atefi.ns@iums.ac.ir

## Person responsible for updating data

#### Contact

**Name of organization / entity**  
Iran University of Medical Sciences  
**Full name of responsible person**  
Niloufar Najar Nobari  
**Position**  
assistant professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Dermatology  
**Street address**  
Hazratb rasool akram hospital, mansoori ave,  
sattarkhan street  
**City**

Tehran  
**Province**  
Tehran  
**Postal code**  
۱۳۴۵۶۱۳۱۳۱  
**Phone**  
+98 21 6651 6001  
**Email**  
niloofar.nobari@yahoo.com

## 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