

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

25 Oct 2020

### Investigating the efficacy and safety of N-Acetyl Cysteine (NAC) inhalation spray in controlling the symptoms of patients with COVID-19

#### Protocol summary

##### Study aim

Investigating the efficacy and safety of N-acetyl-cysteine (NAC) inhalation spray in controlling the symptoms of patients with COVID-19

##### Design

This study is a single-center, prospective, randomized, open-labeled, controlled, parallel phase 3 clinical trial.

##### Settings and conduct

Patients who is admitted to Baqiyatallah hospital, and is meet the inclusion criteria, is entered to the study are randomly assigned into two groups of intervention and control.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Age: equal or more than 18 years; The patient have written consciously and freely consent to participate in the study; The patient's clinical symptoms (dry cough, shortness of breath, fever) confirm COVID-19; Confirmed diagnosis of COVID-19, with either lung CT-Scan result, which is typical for COVID-19 pulmonary involvement, or RT-PCR confirmation; Less than 7 days have passed since the onset of symptoms; Exclusion criteria: history of allergy to ingredients; The patient is in another clinical trial at the same time; The patient needs to receive medical care from the intensive care unit; Pregnancy; Lactation

##### Intervention groups

Intervention group: NAC nasal spray (200 microgram/puff) 1 puff 12 hours, for 7 days (In addition to routine treatment according to the latest national guideline for the treatment of new corona-virus). Control group: routine treatment according to the latest national guideline for the treatment of new corona-virus.

##### Main outcome variables

Clinical symptoms changes (dry cough, respiratory distress, fever)

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20080901001165N55**  
Registration date: **2020-05-23, 1399/03/03**  
Registration timing: **registered\_while\_recruiting**

Last update: **2020-05-23, 1399/03/03**

Update count: **0**

##### Registration date

2020-05-23, 1399/03/03

##### Registrant information

##### Name

Yunes Panahi

##### Name of organization / entity

Baqiyatallah University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8821 1524

##### Email address

yunespanahi@bmsu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-05-13, 1399/02/24

##### Expected recruitment end date

2020-08-14, 1399/05/24

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Investigating the efficacy and safety of N-Acetyl Cysteine (NAC) inhalation spray in controlling the symptoms of

patients with COVID-19

## Public title

Investigating the efficacy and safety of N-Acetyl Cysteine (NAC) inhalation spray in controlling the symptoms of patients with COVID-19

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Age: equal or more than 18 years; The patient have written consciously and freely consent to participate in the study; The patient's clinical symptoms (dry cough, shortness of breath, fever) confirm COVID-19. Confirmed diagnosis of COVID-19, with either lung CT-Scan result, which is typical for COVID-19 pulmonary involvement, or RT-PCR confirmation. Less than 7 days have passed since the onset of symptoms.

### Exclusion criteria:

History of allergy to this nasal spray ingredients; The patient is in another clinical trial at the same time; The patient needs to receive medical care from the intensive care unit; Pregnancy; Lactation.

## Age

From **18 years** old

## Gender

Both

## Phase

3

## Groups that have been masked

*No information*

## Sample size

Target sample size: **72**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Block Randomization method is used to randomized the patients. In this method, the number of people assigned to each group is usually almost equal. Blocks are formed based on the considered variables and within each block, half of the people are involved and half are considered as witnesses. The main goal in this method is to balance the number of participants in each group.

## 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 Baqiyatallah University of Medical Science

## Street address

Baqiyatallah University of Medical Science, south Sheikh-Bahaei St., Mollasadra St., Vanak Sq., Tehran, Iran

## City

Tehran

## Province

Tehran

## Postal code

1435916471

## Approval date

2020-05-02, 1399/02/13

## Ethics committee reference number

IR.BMSU.REC.1399.123

## 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

Clinical symptoms (dry cough)

#### Timepoint

Daily monitoring, but the result of baseline (before the initiation of intervention), and day 7 from the initiation, is recorded.

#### Method of measurement

Physical examination, questionnaire

### 2

#### Description

Clinical symptoms (respiratory distress)

#### Timepoint

Daily monitoring, but the result of baseline (before the initiation of intervention), and day 7 from the initiation, is recorded.

#### Method of measurement

Pulse-oxymetry device

### 3

#### Description

Clinical symptoms (fever)

#### Timepoint

Daily monitoring, but the result of baseline (before the initiation of intervention), and day 7 from the initiation, is recorded.

#### Method of measurement

Thermometer

## Secondary outcomes

### 1

#### Description

Lab. tests changes

#### Timepoint

Daily monitoring, but the before the intervention initiation (baseline) and day 7 results will recorded on designed checklist.

#### Method of measurement

Blood sample, laboratory analysis

### 2

#### Description

Side effects

#### Timepoint

Daily monitoring, but the before the intervention initiation (baseline) and day 7 results will recorded on designed checklist.

#### Method of measurement

Physical examination

## Intervention groups

### 1

#### Description

Intervention group: NAC inhalation spray (200 microgram NAC/puff) 1 puff every 12 hours, for 7 days (In addition to routine treatment according to the latest national guideline for the treatment of new corona-virus)

#### Category

Treatment - Drugs

### 2

#### Description

Control group: Routine treatment according to the latest national guideline for the treatment of new corona-virus.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Baqiyatallah hospital

##### Full name of responsible person

Mostafa Ghanei

##### Street address

Baqiyatallah hospital, Mollasadra St., Vanak Sq., Tehran, Iran.

##### City

Tehran

##### Province

Tehran

##### Postal code

1435916471

#### Phone

+98 21 8245 5393

#### Email

mghaneister@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Bagheiat-allah University of Medical Sciences

##### Full name of responsible person

Gholamhosein Alishiri

##### Street address

Baqiyatallah University of Medical Science, south Sheikh-Bahaei St., Mollasadra St., Vanak Sq., Tehran, Iran.

##### City

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##### Province

Tehran

##### Postal code

1435916471

##### Phone

+98 21 8245 5393

##### Email

R.bmsu@yahoo.com

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Bagheiat-allah University of Medical Sciences

#### Proportion provided by this source

80

#### 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

### 2

#### Sponsor

##### Name of organization / entity

Sina Darou Laboratories Company

##### Full name of responsible person

Dr. Rezaeiyan

##### Street address

Sina Darou Laboratories Company, Shahid Gomnam St., 52th Boulevard, 15th km of Karaj special road

##### City

Tehran

##### Province

Tehran

##### Postal code

1388167311

**Phone**

+98 21 4419 4521

**Email**

info@sinadarou.com

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

No

**Title of funding source**

Baqiyatallah University of Medical Science

**Proportion provided by this source**

20

**Public or private sector**

Private

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

Industry

## Person responsible for general inquiries

**Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Parisa Kianpour

**Position**

Specialist

**Latest degree**

Specialist

**Other areas of specialty/work**

Pharmacotherapy

**Street address**

Pharmacy faculty, Tehran University of Medical Science, 16-Azar St., Enghelab Sq., Tehran, Iran.

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parisa\_kianpour@yahoo.com

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Bagheiat-allah University of Medical Sciences

**Full name of responsible person**

Yunes Panahi

**Position**

Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Critical Care Pharmacotherapy

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Baqiyatallah University of Medical Science, south Sheikh-Bahaei St., Mollasadra St., Vanak Sq., Tehran, Iran.

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Parisa Kianpour

**Position**

Specialist

**Latest degree**

Specialist

**Other areas of specialty/work**

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parisa\_kianpour@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**

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