

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Sep 2021

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

Tehran

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.

City

Tehran

Province

Tehran

Postal code

1417614411

Phone

+98 21 6695 4709

Email

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

Street address

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

City

Tehran

Province

Tehran

Postal code

1435916471

Phone

+98 21 8245 5393

Email

Yunespanahi@yahoo.com

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

Pharmacotherapy

Street address

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

City

Tehran

Province

Tehran

Postal code

1417614411

Phone

+98 21 6695 4709

Email

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