Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 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)

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+98 21 8821 1524

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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-oxymetery 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.
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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.
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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
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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

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Person responsible for scientific inquiries

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Full name of responsible person
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Position
Professor

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Other areas of specialty/work
Critical Care Pharmacotherapy

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Person responsible for updating data

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Full name of responsible person
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Position
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Latest degree
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Other areas of specialty/work
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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

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