Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Nov 2026

The effect of inhaled bromhexine on clinical and laboratory symptoms and COVID-19

Protocol summary

Study aim
The aim of this study is to compare the effect of the bromhexine hydrochloride solution for inhalation and placebo on the improvement of respiratory condition in patients with COVID-19 by focusing on the severity of the cough.

Design
A double-blinded randomized, placebo-controlled clinical trial with parallel groups, on 78 patients. Blocks of 4 will used for randomization

Settings and conduct
The study is carried out in Semnan Kowsar Hospital and in an interventional approach. The patients are assigned into two groups, intervention group will receive the bromhexine hydrochloride solution for inhalation, 8 mg, three times a day for 7 days via a nebulizer mask and the control group receives placebo (normal saline in the same volume as inhaled bromhexine) in the same way and time pattern.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Positive result for PCR and Age more than 18 years Exclusion criteria: Oxygen saturation level of lower than 90% and hypotension

Intervention groups
The way to get the medicine to the test group is that 8mg of Girambromhexine inhaled through a nebulizer mask every 8 hours for one week in Kausar Semnan hospital and 8mg of normal saline inhaled every 8 hours for 7 days to the control group.

Main outcome variables
Comparison of the respiratory function of patients based on cough severity, arterial blood oxygen saturation and carbon dioxide level as indicators of respiratory function.

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20230514058188N1**
Registration date: **2023-06-13, 1402/03/23**
Registration timing: **registered_while_recruiting**

Last update: **2023-06-13, 1402/03/23**
Update count: **0**

Registration date
2023-06-13, 1402/03/23

Registrant information
Name
Sima gharibshah
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 23 3343 4253
Email address
simagharibshah@gmail.com

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2023-06-10, 1402/03/20
Expected recruitment end date
2023-10-11, 1402/07/19
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of inhaled bromhexine on clinical and laboratory symptoms and COVID-19

Public title
The effect of inhaled bromhexine on clinical symptoms

and recovery of COVID-19

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with COVID-19 confirmed by PCR Patients with respiratory symptoms including caugh and dyspnea

Exclusion criteria:

Need to mechanical ventilation Pregnancy or lactating Peptic ulcer

Age

From **18 years** old to **90 years** old

Gender

Both

Phase

3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **78**

Randomization (investigator's opinion)

Randomized

Randomization description

For randomization, a block randomization method will be used. In the study, the allocation of samples is based on a random sequence provided by a statistical expert using statistical software. The block size will be 6. Meanwhile, the tool which is used for generating random-sequence blocks is a web-based software available at https://kitset.ir/numbers/random.

Blinding (investigator's opinion)

Double blinded

Blinding description

The blinding of the study is such that the outcome assessor and biostatistician do not know the content of the intervention. For administration, the drug will be given to the clinical care provider for administration by mentioning the administration method. The outcome assessor records the outcome based on the patient's identity number according to the randomization table, and the data collected based on the number and mention of the first and second intervention is provided to the biostatistician for analysis.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Semnan University of Medical Sciences

Street address

kosar hospital , Amin Street , Golestan Town , Semnan

City

Semnan

Province

Semnan

Postal code

3519899951

Approval date

2023-05-01, 1402/02/11

Ethics committee reference number

IR.SEMUMS.REC.1402.015

Health conditions studied

1

Description of health condition studied

Dyspnea

ICD-10 code

R06

ICD-10 code description

Abnormalities of breathing

Primary outcomes

1

Description

Cough Severity

Timepoint

Before intervention and daily up to 7 day after intervention

Method of measurement

Visual Analogue Score

Secondary outcomes

1

Description

Arterial blood O2 saturation

Timepoint

Before intervention and daily up to 7 days after intervention

Method of measurement

Atrial blood gas measurment

2

Description

Arterial blood carbon dioxide level

Timepoint

Before intervention and daily up to 7 days after intervention

Method of measurement

Atrial blood gas measurment

Intervention groups

1

Description
Intervention group: Patients will receive bromhexine hydrochloride solution for inhalation (Mucolin ampoule 4 mg/2 ml, manufactured by Daru Pharmaceutical Company, Iran) 8 mg every 8 hours via a nebulizer mask for 7 days.
Category
Treatment - Drugs

2

Description
Control group: The patients will receive placebo (normal saline in a volume equal to inhaled bromhexine) every 8 hours through a nebulizer mask for 7 days.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Kowsar hospital
Full name of responsible person
Sima Gharibshah
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Amin Street , Golestan Town
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Semnan University of Medical Sciences
Full name of responsible person
Dr. Majid Mirmohammadkhani
Street address
Central Office of Semnan University of Medical Sciences, Basidj Blvd.
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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
Semnan 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
Semnan University of Medical Sciences
Full name of responsible person
Mohammad Memarian
Position
Assistant professor
Latest degree
Subspecialist
Other areas of specialty/work
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
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Position
Researcher

Latest degree
Medical doctor

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General Practitioner

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Not applicable

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
All data will be presented anonymously.

When the data will become available and for how long
From the March of 2024

To whom data/document is available
All researchers and workers in the medical sciences

Under which criteria data/document could be used
The condition of using the data is that if it is used in scientific research, the name of the researchers of this project should be included.

From where data/document is obtainable
If needed, can be available by contacting the person responsible for general inquiries, Dr. Mohammad Memarian via email: draria2014@gmail.com.

What processes are involved for a request to access data/document
First, with one of the mentioned methods, he informs the researcher what information he needs; Then, if possible, the information will be sent to them one week later.

Comments