

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 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 be 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 cough 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 measurement

2

Description

Arterial blood carbon dioxide level

Timepoint

Before intervention and daily up to 7 days after intervention

Method of measurement

Atrial blood gas measurement

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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Email

rds@semums.ac.ir

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

Contact

Name of organization / entity

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Full name of responsible person

Mohammad Foroozeshfard

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Sima Gharibshah

Position

Researcher

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Email

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