

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Verification of the efficacy of bromhexine hydrochloride in the prevention of COVID-19 disease

Protocol summary

Study aim

The efficacy of bromhexine hydrochloride in the prevention of COVID-19 disease will be studied.

Design

A clinical trial with a control group, with parallel groups, simple-randomly assigned to intervention and control groups, Phase 2, 3500 close contacts of patients with COVID-19 disease

Settings and conduct

This study will be performed in Imam Reza Hospital in Tabriz, Iran. 3500 contacts of patients with COVID-19 will be selected and randomly divided into two groups. The control group will receive a placebo and the intervention group will receive 8 mg bromhexine tablets every 8 hours for 14 days. Lung CT scan, Coronavirus PCR test, and IgM and IgG levels will be checked.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 18 to 80 years old; both genders; having household contact, having contact with a COVID-19 case without a facemask that is confirmed with RT-PCR or with clinical or radiographic evidence of pneumonia, and acute respiratory distress syndrome (ARDS); lack of the clinical symptoms of COVID-19 (fever, cough, dyspnea, having difficulty in breathing, sore throat, severe fatigue, GI symptoms); lack of chronic respiratory or other illnesses with symptoms that are mostly confused with symptoms of COVID-19 disease. Exclusion criteria: less than 18 years old; severe renal failure; severe liver disease; pregnancy, breastfeeding, or a positive pregnancy test result; subjects who receive immune-modulating drugs for other diseases; participants in other clinical trials for COVID-19 within 30 days before or after randomization; participants in other drugs clinical trial; having an allergy to bromhexine hydrochloride or its ingredients

Intervention groups

The intervention group will receive 8 mg bromhexine tablets every 8 hours for 14 days.

Main outcome variables

Lung CT scan, coronavirus PCR test, and biochemical, immunological, and clinical tests

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200317046797N7**

Registration date: **2020-09-14, 1399/06/24**

Registration timing: **registered_while_recruiting**

Last update: **2020-09-14, 1399/06/24**

Update count: **0**

Registration date

2020-09-14, 1399/06/24

Registrant information

Name

Sepideh Zununi Vahed

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3336 9331

Email address

sepide.zununi@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-20, 1399/02/01

Expected recruitment end date

2020-09-20, 1399/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Verification of the efficacy of bromhexine hydrochloride in the prevention of COVID-19 disease

Public title

The efficacy of bromhexine hydrochloride in the prevention of COVID-19 disease

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

18 Years to 80 years old Both genders Having household contact or contact in less than 1.5 meters for more than one hour, or exposed without facemask with a COVID-19 case confirmed with RT-PCR or with clinical or radiographic evidence of pneumonia, acute respiratory distress syndrome (ARDS) Free of the COVID-19 disease symptoms (fever, cough, dyspnea, difficulty breathing, sore throat, severe fatigue, headache, GI symptoms) Free from chronic respiratory or other illnesses with symptoms confused with symptoms of COVID-19 disease Signed consent form

Exclusion criteria:

Less than 18 years Severe renal failure Severe liver disease Pregnant or breastfeeding woman or with a positive pregnancy test result Subjects on immune-modulating drugs for other diseases subjects on other clinical trials for COVID-19 within 30 days before or after randomization Subjects in other drug clinical trial Having an allergy to bromhexine hydrochloride or its ingredients

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **3500**

Randomization (investigator's opinion)

Randomized

Randomization description

Based on the inclusion and exclusion criteria, the subjects will be randomized into two (control and experimental) groups via balanced block randomization. The groups will be generated by a computer-based random sequence generator and individuals will enter the assigned groups based on their entry sequence.

Blinding (investigator's opinion)

Double blinded

Blinding description

This is a double-blind study in which both researchers and contacts will not be aware of the individuals' drug administration. Placebo and the main drug will be dispensed by a third person in uniform packages with defined codes. Instructions on the drug consumption will

not be seen by the prescriber.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Tabriz University of Medical Sciences

Street address

Tabriz University of Medical Sciences, Golgasht Street

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Approval date

2020-04-05, 1399/01/17

Ethics committee reference number

IR.TBZMED.REC.1399.553

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**

Test for the presence or absence of corona virus nucleic acid

Timepoint

15 days after the intervention

Method of measurement

Real-time PCR

2**Description**

Serum levels of IgM and IgG

Timepoint

15 days after the intervention

Method of measurement

Immunological test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention group will receive 8 mg bromhexine tablets every 8 hours for 14 days.

Category

Prevention

2

Description

Control group: They will receive 3 placebo tablets a day for 14 days.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Imamreza Hospita of Tabriz

Full name of responsible person

Dr Khalil Ansarin

Street address

Lung Ward, 4th floor Of Imam Reza Hospital, Golgasht st.

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Tabriz

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5166614756

Phone

+98 41 3334 7054

Email

imamreza@tbzmed.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr Mohammad Samiei

Street address

3th floor of Tabriz University of Medical Sciences
Central Building, Golgasht Street, Tabriz

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Email

Samiei.moh@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Dr Khalil Ansarin

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

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Person responsible for updating data

Contact

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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

Not applicable

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