Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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
Immamreza Hospita of Tabriz
Full name of responsible person
Dr Khalil Ansarin
Street address
Lung Ward, 4th floor Of Imam Reza Hospital, Golgasht st.
City
Tabriz
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East Azarbaijan
Postal code
5166614756
Phone
+98 41 3334 7054
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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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5166614766
Phone
+98 41 3335 7310
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 scientific inquiries

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Position

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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