# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

23 Feb 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
**Province**
East Azarbaijan
**Postal code**
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
**City**
Tabriz
**Province**
East Azarbaijan
**Postal code**
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**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
**Street address**
Lung Ward, 4th floor Of Imam Reza Hospital, Golgasht st.
**City**
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**Province**
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**Postal code**
5166614756
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## Person responsible for scientific 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**

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## Person responsible for updating data

**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**

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dr.ansarin@gmail.com

## 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