# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

23 Feb 2026

## Verification of the efficacy of Bromhexine-hydrochloride in treatment of patients with COVID19 disease

### Protocol summary

**Study aim**

This is a clinical trial that aims to confirm the effectiveness of this drug in preventing the deterioration of a patient with COVID19 from deterioration to hospitalization.

**Design**

Data will be collected by physicians and completed by completing a pre-made work protocol in admission articles and blood and throat PCR laboratory samples and will be sent to laboratories 24/7. The results of the patient's treatment and clinical course are followed up and recorded daily. All collected data are analyzed in SPSS software.

**Settings and conduct**

A placebo-controlled study involving 1,300 patients with COVID19 at Imam Reza Hospital based on clinical signs, imaging studies, and pre-PCR examination of nasopharyngeal biopsy results available the following day (at least 650 positive PCR cases target to report verified items).

**Participants/Inclusion and exclusion criteria**

Inclusion criteria: - Male and female patients, 18 years and older All patients must meet all criteria for probable or confirmed COVID19 disease according to CSTE guidelines: Exclusion criteria Male and female patients under 18 years - Participate in other ongoing studies. - Pregnant or lactating woman Severe liver disease Severe kidney failure Refusal by the treating physician for clinical imbalance - Advanced active malignancy Patient in other clinical trials for COVID-19 within 30 days before / after ICF - Known allergies

**Intervention groups**

The intervention group will receive 8 mg bromhexine tablets every 8 hours for 14 days. Control group: receiving 3 placebo tab per day for 14 day

**Main outcome variables**

1. Evaluation of the efficacy of the drug in the parameters of clinical symptoms in comparison with the placebo group; 2. To examine the trend of laboratory changes (in CRP, LDH, NLR promotion) in bromhexine and placebo groups; 3. To evaluate the initial changes in IgM and IgG levels in the groups treated with bromhexine and placebo

### General information

**Reason for update**

**Acronym**

COV-19

**IRCT registration information**

IRCT registration number: **IRCT20200818048444N1**
Registration date: **2020-09-15, 1399/06/25**
Registration timing: **prospective**

Last update: **2020-12-13, 1399/09/23**
Update count: **2**

**Registration date**

2020-09-15, 1399/06/25

**Registrant information**

**Name**

Khalil Ansarin

**Name of organization / entity**

**Country**

Iran (Islamic Republic of)

**Phone**

+98 41 3337 8093

**Email address**

dr.ansarin@gmail.com

**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2020-09-22, 1399/07/01

**Expected recruitment end date**

2020-10-22, 1399/08/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Verification of the efficacy of Bromhexine-hydrochloride in treatment of patients with COVID19 disease

**Public title**

Verification of the efficacy of Bromhexine-hydrochloride in treatment of patients with COVID19 disease

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

18 years and older, both sexes Having home contact, unmasked contact with a patient with Covid-19 confirmed by RT-PCR or clinical evidence or radiography of pneumonia and acute respiratory distress syndrome (ARDS); No clinical signs of Covid-19 (fever, cough, dyspnea, shortness of breath, sore throat, extreme tiredness, digestive problems); No chronic respiratory problems or other illnesses that are mistaken for symptoms of COVID-19

**Exclusion criteria:**

Involvement with any other ongoing studies. Pregnant or breast feeding woman or with positive pregnancy test result for fetal safety Severe liver disease as a strong confounding factor Severe renal failure as a strong confounding factor Refusal by attending physician for no clinical equipoise Advanced active malignancy as a strong confounding factor Patient in other clinical trials for COVID-19 within 30 days before/after ICF as a confounding factor/s Other patient characteristics (not thought to be related to underlying COVID-19) that portend a very poor prognosis (e.g, severe liver failure, severe renal failure, and etc. May impact primary and other clinical endpoints- Known allergy to study drug or its ingredients related to renin-angiotensin system (RAS), or frequent and/or severe allergic reactions with multiple medications for patient protection purposes Other uncontrolled disease, as judged by investigators that may influence study endpoint and other clinical outcome

**Age**

From **18 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant

**Sample size**

Target sample size: **1300**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

According to the entry and exit criteria, through random allocation by variable block method, individuals are divided into two groups of control and experimental. Using Random Sequence Generator, groups are created and people are placed in one of these two groups based on the reference sequence.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

This study is a two-way blind study. In this study, the subject and the researcher are both unaware of the drug used by individuals. The placebo and the main drug are placed in similar boxes with specific codes and are delivered to the patient by a third party. Medication information will not be visible to the therapist.

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

Regional Committee on Research Ethics (Studies in Human Subjects)

**Street address**

Third Floor / Tabriz University of Medical Sciences, Central Building No. 2/Golgasht St.

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5166614766

**Approval date**

2020-08-24, 1399/06/03

**Ethics committee reference number**

IR.TBZMED.REC.1399.827

## 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 nucleic acid in the corona virus

**Timepoint**
15 days after the intervention
**Method of measurement**
real-time PCR

**2**

**Description**
Serum IgM and IgG levels
**Timepoint**
15 days after the intervention
**Method of measurement**
Immunology 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: will receive 3 placebo tablets per day for 14 days.
**Category**
Placebo

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Imam Reza Hospital
**Full name of responsible person**
Khalil Ansarin
**Street address**
Imam Reza Hospital, Golgasht St.
**City**
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## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Tabriz University of Medical Sciences
**Full name of responsible person**
Dr. Mohammad Samiei
**Street address**
Central Building of University of Medical Sciences/ Golgasht St./ Azadi St./ Tabriz
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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?**
No
**Title of funding source**
Ministry of Health and Medical Education
**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**
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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## Person responsible for updating data

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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**
No - There is not 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**
No - There is not a plan to make this available
**Data Dictionary**
Yes - There is a plan to make this available
**Title and more details about the data/document**
All data can potentially be shared after unidentified individuals.
**When the data will become available and for how long**
Spring 1400
**To whom data/document is available**
Data is allowed for all researchers after submitting an access request and confirming it
**Under which criteria data/document could be used**
In order to use the data, researchers must first identify and send the required items and data upon request, after which the data will be delivered.
**From where data/document is obtainable**
By email dr.ansarin@gmail.com or postal code: 5142954481
**What processes are involved for a request to access data/document**
The researcher must state his request in a letter. After agreeing to his request, the data will be emailed to him in Excel or Spss.
**Comments**