Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The Effect of Bromhexine Hydrochloride versus Placebo on Clinical Outcomes of Patients with COVID-19 disease: a Randomized Controlled Trial

Protocol summary

Study aim
Verifying the effect of the bromhexine hydrochloride on the COVID19 disease compared to placebo
Design
Two patient groups receiving either the Bromhexine hydrochloride 8 mg or placebo every 8 hours for 16 days
Settings and conduct
EmamReza Hospital
Participants/Inclusion and exclusion criteria
COVID19 patients diagnoses according to three diagnostic criteria of this protocol and are 18 year of age or older
Intervention groups
Two patient groups receiving either the Bromhexine hydrochloride 8 mg or placebo every 8 hours for 16 days
Main outcome variables
ICU transfer, Intubation and Mechanical Ventilation, Survival/Mortality

General information

Reason for update
Acronym
BH8MGIRINT
IRCT registration information
IRCT registration number: **IRCT20200818048444N2**
Registration date: **2020-12-31, 1399/10/11**
Registration timing: **registered_while_recruiting**

Last update: **2020-12-31, 1399/10/11**
Update count: **0**
Registration date
2020-12-31, 1399/10/11

Registrant information
Name
Khalil Ansarin
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 41 3337 8093
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2020-11-14, 1399/08/24
Expected recruitment end date
2021-03-20, 1399/12/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The Effect of Bromhexine Hydrochloride versus Placebo on Clinical Outcomes of Patients with COVID-19 disease: a Randomized Controlled Trial

Public title
The Effect of Bromhexine Hydrochloride on Clinical Outcomes of Patients with COVID-19 disease
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
I-New laboratory confirmed diagnosis of SARS-CoV-2 via reverse transcriptase polymerase chain reaction as per the World Health Organization protocol, by nucleic acid based isothermal amplification, or by antigen testing OR II- Clinical suspicion of COVID-19 disease and acute onset

(less than 10 days) and of AT LEAST ONE of the following conditions:• Loss of smell or taste• Cough or shortness of breath / dyspnea• Fever (body temperature > 38.5°)• PLUS Findings on chest-X ray or computer tomography suggestive of COVID-19 OR III- Clinical suspicion of COVID-19 disease and acute onset (less than 10 days) of AT LEAST TWO of the following conditions: • Chills or rigor • Conjunctivitis • Sore throat • Gastrointestinal symptoms • Headaches • Fatigue or malaise • Aches or pain PLUS Findings on chest-X ray or computer tomography suggestive of COVID-19 18 years and older Informed consent from the patient (or legally authorized substitute decision maker).

Exclusion criteria:

The exclusion criteria are: 1) Admitted to the intensive care unit at the time of screening; 2) Imminent initiation or treatment with invasive mechanical ventilation at the time of screening; 3) Imminent death according to the judgement of the most responsible physician; 4) Receiving palliative care; 5) Known history of severe liver or kidney dysfunction; 6) On treatment with Bromhexine hydrochloride at the time of screening; 7) Known allergy to bromhexine hydrochloride; 8) Pregnancy or breastfeeding (including baby to breast, bottle feeding mother's expressed breast milk); 9) Previous enrollment in this trial (Enrollment in another clinical trial does not preclude enrollment in this trial)

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **400**

Randomization (investigator's opinion)

Randomized

Randomization description

1:1 randomization, centralized web-based randomization and according to the entry and exit criteria, through random allocation by balanced 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 for Research Ethics(Human Subject Studies(91000001))

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

2020-12-21, 1399/10/01

Ethics committee reference number

IR.TBZMED.REC.1399.881

Health conditions studied

1

Description of health condition studied

COVID19

ICD-10 code

U07.1

ICD-10 code description

COVID19

Primary outcomes

1

Description

Survival

Timepoint

28 days after start of the treatment

Method of measurement

Follow up from hospital files and phone F/U in subjects who discharged earlier

2

Description

levels of CRP, LDH, Troponin, Ferritin

Timepoint

Day 1 and 28 days after treatment

Method of measurement

Standard laboratory hematology and biochemistry tests

3

Description
NLR (Neutrophil to Lymphocyte Ratio) and D-Dimer
Timepoint
Day 1 and 28 days after treatment
Method of measurement
Standard laboratory hematology and biochemistry tests

4

Description
ICU transfer rate
Timepoint
28 days after start of the treatment
Method of measurement
Follow up from hospital files and phone F/U in subjects who discharged earlier

5

Description
Intubation and Mechanical Ventilation
Timepoint
28 days after start of the treatment
Method of measurement
Follow up from hospital files and phone F/U in subjects who discharged earlier

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Bromhexine 8 mg every 8 hourly P O produced by Tolidaru.
Category
Treatment - Drugs

2

Description
Control group: Placebo as tablets that has been made similar to bromhexine and provided by the same drug company, Tolidaru, producing the bromhexine hydrochloride administered every 8 hourly p o for 16 days
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
EmamReza Hospital, Tabriz University of Medical Sciences
Full name of responsible person
Khalil Ansarin
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Health Vice-Chancellor of Ministry of Health and Medical Education (MOHME)
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 of Medicine

Latest degree
Subspecialist

Other areas of specialty/work
Internal Medicine

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Position
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Latest degree
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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
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
Yes - There is 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 the individuals.

When the data will become available and for how long
Second quarter of 2021

To whom data/document is available
Access to data will be 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. Upon agreeing to his request, the data will be emailed to him in Excel or Spss.

Comments