

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jun 2026

### Evaluation of the efficacy of N-acetylcysteine and Bromhexine compared with Standard Care in Preventing Hospitalization of Outpatients with COVID-19: A double-blind randomized clinical trial

#### Protocol summary

##### Study aim

Comparison of the effect of acetylcysteine and bromhexine on the improvement and prevention of hospitalization in outpatients

##### Design

One group of patients will be given oral acetylcysteine 600 mg twice daily for 5 days and another group will be given 8 mg bromhexine tablets three times daily and the control group will receive only the usual treatments prescribed to the other two groups. for 5 days. Referral, on day 7 and day 14, patients' oxygen levels and hospitalization and death are checked.

##### Settings and conduct

This double-blind clinical trial is conducted on 225 outpatients at the Dibaj City Service Center. After the initial diagnosis of the covid-19 disease, according to the symptoms of the patients by the doctor, first of all, the pharynx and nose sample for RT-PCR test for The diagnosis of covid-19 is made in the health service center and after the positive test, the patient is included in the study. First, the blood oxygen level of the patients was measured with a pulse oximeter and patients were randomly divided into one of three groups. Patients are then asked to visit the clinic on the 7th and 14th days to check their oxygen levels.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria include: • Adult patients aged 18 to 80 years referred to Dibaj Municipal Service Center • Outpatients with Covid-19 symptoms after positive Covid-19 RT-PCR test • Oxygen level 98-92% Exclusion criteria: • Pregnancy and lactation .Patients taking nitroglycerin.

##### Intervention groups

This clinical trial is performed on outpatients Covid 19. One group of patients is given oral acetylcysteine 600 mg twice daily for 5 days and another group is given 8 mg bromhexine tablets three times daily for 5 days, The

control group will receive only the usual treatments prescribed to the other two groups.

##### Main outcome variables

Duration of recovery, Duration of hospitalization, Death

#### General information

##### Reason for update

Due to re-judgment of the proposal

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220302054167N1**

Registration date: **2022-04-29, 1401/02/09**

Registration timing: **registered\_while\_recruiting**

Last update: **2023-08-13, 1402/05/22**

Update count: **1**

##### Registration date

2022-04-29, 1401/02/09

##### Registrant information

###### Name

Anahita Eslami-ghayour

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 81 3824 5383

###### Email address

anahitaeslami1995@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-03-10, 1400/12/19

##### Expected recruitment end date

2022-05-09, 1401/02/19

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Evaluation of the efficacy of N-acetylcysteine and Bromhexine compared with Standard Care in Preventing Hospitalization of Outpatients with COVID-19: A double-blind randomized clinical trial

**Public title**

The effect of acetylcysteine and bromhexine on the improvement and prevention of hospitalization in outpatients with Covid-19

**Purpose**

Prevention

**Inclusion/Exclusion criteria****Inclusion criteria:**

Outpatients with Covid-19 symptoms after positive Covid-19 RT-PCR test Oxygen level 98-92%

**Exclusion criteria:**

• Dissatisfaction of the patient or their relatives to participate in the study • Pregnancy and lactation Evidence of pulmonary involvement and the need for hospitalization or referral to an infectious disease specialist Prohibition of N-acetylcysteine and bromhexine as a history of allergy and anaphylactic shock

**Age**

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

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Investigator

**Sample size**

Target sample size: **225**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

We will use a six-block randomized method for patient allocation. Sheets will be prepared on which two sheets of letters "A", two sheets of "B" and two sheets of "C" will be written. These will be mixed up and placed in the desk drawer. When the patient is eligible, a card is randomly drawn and the patient is placed in groups "A", "B", "C". Notably, a particular card is not returned to the drawer until all six cards have been drawn once. This process of random allocation continues for the next six patients until the desired sample size of 225 patients is obtained.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Both intervention and control groups will receive injectable drugs with the same appearance, which are marked with a code, and the patient and the examiner

will be unaware of the type of drug used by the patients. Therefore, the study will be conducted in a double-blind manner.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Ethics Committee of Hamadan University of Medical Sciences

**Street address**

Research Ethics Committee, Vice Chancellor for Research and Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Blvd.

**City**

Hamedan

**Province**

Hamadan

**Postal code**

۶۵۱۷۸۳۸۷۳۶

**Approval date**

2022-03-04, 1400/12/13

**Ethics committee reference number**

IR.UMSHA.REC.1400.957

**Health conditions studied****1****Description of health condition studied**

covid-19

**ICD-10 code**

U07.1

**ICD-10 code description**

COVID-19, virus identified

**Primary outcomes****1****Description**

blood Oxygen

**Timepoint**

At the beginning of the study (before the intervention) and 7, 14 days

**Method of measurement**

pulse oximeter

**2****Description**

Cough

**Timepoint**

At the beginning of the study (before the intervention) and 7, 14 days

**Method of measurement**

questionnaire

**3**

**Description**

Shortness of breath

**Timepoint**

At the beginning of the study (before the intervention) and 7, 14 days

**Method of measurement**

questionnaire

**4**

**Description**

Sore throat

**Timepoint**

At the beginning of the study (before the intervention) and 7, 14 days

**Method of measurement**

questionnaire

**Secondary outcomes**

**1**

**Description**

Time to recover from the desired symptoms

**Timepoint**

daily

**Method of measurement**

questionnaire

**2**

**Description**

Duration of hospitalization

**Timepoint**

At the beginning of the study (before the intervention) and 7, 14 days

**Method of measurement**

questionnaire

**3**

**Description**

Death

**Timepoint**

At the beginning of the study (before the intervention) and 7, 14 days

**Method of measurement**

questionnaire

**Intervention groups**

**1**

**Description**

Intervention group: The first group was a group of patients taking oral acetylcysteine(Hakim company) 600 mg twice daily for 5 days

**Category**

Treatment - Drugs

**2**

**Description**

Intervention group: The second method is for patients who take 8 mg of bromhexine tablets (Tolid Daroo) three times a day for 5 days.

**Category**

Treatment - Drugs

**3**

**Description**

Control group: They will receive only the usual treatments prescribed for the other two groups. All patients received naproxen 250 mg twice daily for five days, famotidine 20 mg once daily for ten days, vitamin D 50,000 per week for four weeks, and vitamin C 1,000 mg daily.

**Category**

Treatment - Drugs

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Dibaj Urban Health Services Center

**Full name of responsible person**

Mohsen Norozi

**Street address**

Kamalabad St., Dibaj Clinic

**City**

hamedan

**Province**

Hamadan

**Postal code**

6516768567

**Phone**

+98 81 3833 1024

**Email**

anahitaeslami1995@gmail.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

DR. Mhamad Khazaii

**Street address**

4th floor,University of Medical Sciences, Shahid

Fahmideh St.,Research Square

**City**

Hamedan

**Province**

Hamadan

**Postal code**

۶۵۱۷۸۳۸۷۳۶

**Phone**

+98 81 3131 0000

**Email**

it.amoozesh@umsha.ac.ir

**Web page address**

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Hamedan 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**

Hamedan University of Medical Sciences

**Full name of responsible person**

Anahita Eslami-Ghayour

**Position**

medical doctor

**Latest degree**

Medical doctor

**Other areas of specialty/work**

General Practitioner

**Street address**

No. 25, Jihad Alley, 18 meters from Fajr, Ostadan St.

**City**

Hamedan

**Province**

Hamadan

**Postal code**

6516866818

**Phone**

+98 81 3824 5383

**Email**

anahitaeslami1995@gmail.com

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Fariba keramat

**Position**

medical doctor

**Latest degree**

Specialist

**Other areas of specialty/work**

Infectious diseases

**Street address**

Pasteur Crossroads, Farshchian Educational and Medical Center, Hamedan

**City**

hamedan

**Province**

Hamadan

**Postal code**

6516866818

**Phone**

+98 81 3827 4184

**Email**

keramat@umsha.ac.ir

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Fateme Shahbazi

**Position**

PhD student in epidemiology

**Latest degree**

Master

**Other areas of specialty/work**

Epidemiology

**Street address**

Research Square, Shahid Fahmideh St., hamedan University of Medical Sciences

**City**

Hamedan

**Province**

Hamadan

**Postal code**

۶۵۱۷۸۳۸۷۳۶

**Phone**

+98 81 3131 0000

**Email**

shahbazif2017@gmail.com

**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is 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**

Not applicable

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

All data is potentially shareable after unidentifiable individuals

**When the data will become available and for how long**

Six months after the results were published

**To whom data/document is available**

Researchers working in academic institutions

**Under which criteria data/document could be used**

For further research purposes and analysis

**From where data/document is obtainable**

Anahita Eslami Ghayour, Hamedan University of medical science

**What processes are involved for a request to access data/document**

Official letter to researchers

**Comments**