

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 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