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

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Iran (Islamic Republic of)

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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.
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Hamedan
Province
Hamadan
Postal code
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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

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Kamalabad St., Dibaj Clinic

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

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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

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Person responsible for updating data

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Full name of responsible person
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PhD student in epidemiology

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Epidemiology

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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