

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jun 2022

Effect of Bromhexine Hydrochloride on clinical improvement and outcome of COVID-19-induced pneumonia

Protocol summary

Study aim

The effect of bromhexine on the course of clinical signs in patients with COVID-19 will be Evaluated.

Design

A clinical trial with a control group, with parallel groups, simple-randomly assigned to intervention and control groups, Phase 3, 60 patients

Settings and conduct

This study will be performed in Imam Reza Hospital, Tabriz, Iran. 60 patients will be divided into two groups (30 in each group) by simple randomization. Patients in the control group will be prescribed a standard regimen. The intervention group will receive Bromhexine 8 mg tablets every 8 hours for 14 days from the beginning of hospitalization. Lungs' CT scan, hospitalization period, need to intubation and mortality rate will be assessed.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with PCR-positive for COVID-19 with mild to moderate pneumonia; 18 Years to 80 Years; both genders. Exclusion criteria: Pregnant or lactating women; patients with an active thrombotic event; severe respiratory failure.

Intervention groups

Intervention group: will receive a standard regimen for COVID-19 plus Bromhexine. Control group: will receive a standard regimen for COVID-19.

Main outcome variables

Symptoms of the disease; mortality rate; hospitalization period

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200317046797N4**

Registration date: **2020-04-14, 1399/01/26**

Registration timing: **prospective**

Last update: **2020-04-14, 1399/01/26**

Update count: **0**

Registration date

2020-04-14, 1399/01/26

Registrant information

Name

Sepideh Zununi Vahed

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-18, 1399/01/30

Expected recruitment end date

2020-05-19, 1399/02/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Bromhexine Hydrochloride on clinical improvement and outcome of COVID-19-induced pneumonia

Public title

Effect of Bromhexine Hydrochloride on patients with COVID-19

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with COVID-19-induced pneumonia confirmed with PCR Patients or authorized family members volunteered to participate in this study and signed informed consent. Both genders 18 to 80 years old

Exclusion criteria:

Patients who are participating in other drug clinical trials
Pregnant or lactating women Patient with active thrombotic event Patients with severe respiratory failure

Age

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

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization will be generated with a computer from 1 to 60. The computer will divide the digits between the two groups. According to the sequences of admission, they will go to the control or the intervention group regarding the computerized random list.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Tabriz University of Medical Sciences

Street address

Tabriz University of Medical Sciences, Golgasht Street

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Tabriz

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Postal code

5166614766

Approval date

2020-04-05, 1399/01/17

Ethics committee reference number

IR.TBZMED.REC.1399.013

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

Patients with COVID-2019

ICD-10 code

U07.1

ICD-10 code description

COVID-19, virus identified

2**Description of health condition studied****ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

Hospitalization days

Timepoint

At baseline and discharge time

Method of measurement

Counting the days

2**Description**

Need for mechanical ventilation

Timepoint

From baseline to discharge time

Method of measurement

Observation and documents

3**Description**

Condition of discharge (death or recovery)

Timepoint

End of hospitalization

Method of measurement

Observation and documents

4**Description**

Period of mechanical ventilation

Timepoint

End of hospitalization

Method of measurement

Documents of hospitalization

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group:30 patients with COVID-19 in addition to a standard regimen will receive Bromhexine 8 mg tablets every 8 hours for 14 days from the beginning of hospitalization

Category

Treatment - Drugs

2

Description

Control group: 30 patients will receive only standard regimen of COVID-2019

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imamreza Hospita of Tabriz

Full name of responsible person

Dr Khalil Ansarin

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Imamreza Hospital, Daneshgah Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

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?

Yes

Title of funding source

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Dr Khalil Ansarin

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

Sepideh Zununi Vahed

Position

Assistant Prof.

Latest degree

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Other areas of specialty/work

Medical Biotechnology

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

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

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

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available