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
City
Tabriz
Province
East Azarbaijan
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
Immamreza Hospita of Tabriz

Full name of responsible person
Dr Khalil Ansarin

Street address
Imamreza Hospital, Daneshgah Street

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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?
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
Internal Medicine

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Person responsible for updating data

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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