Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Efficacy and safety of Ethanol inhalation on early stage of COVID-19 (a clinical trial study)

Protocol summary

Study aim
Evaluation of the effectiveness of inhaled ethanol therapy in the control of Covid-19 disease

Design
Phase 3 clinical trial with a control group, parallel and single-blind type, in which the patient remains unaware of the name of the intervention drug. Random sampling on 86 patients.

Settings and conduct
This study was performed at Issa Bin Maryam Hospital in, Iran on patients who are temporarily hospitalized to receive remedicivir and dexamethasone or are hospitalized for several days in other wards. For patients in the ethanol group the oxygen flow meter or the nebulizer is poured with ethanol 35% .

Participants/Inclusion and exclusion criteria
Eligibility criteria Positive RT-PCR test Less than seven days from onset of symptoms Age 15-69 years; Non-Eligibility criteria Pregnancy History of asthma Alcoholism Epilepsy Contraindications to ethanol Disagreement of the treating physician

Intervention groups
In both groups, standard treatments are given according to the usual procedure. In the intervention group the inhaled ethanol is also added. Inhalation of 10 ml of 70% ethanol with 10 ml of distilled water in an oxygen flow meter with a flow of 2-3 liters per minute, every six hours for 15 minutes for up to five days will be our intervention. If the patient does not accept this method, the same amount of ethanol and distilled water is poured into the cold nebulizer and it is prescribed. In the control group, only 20 ml distilled water is poured into an oxygen flow meter instead of ethanol.

Main outcome variables
Symptoms, SPO2, WBC, CRP

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210725051981N1**
Registration date: **2021-10-19, 1400/07/27**
Registration timing: **prospective**

Last update: **2021-10-19, 1400/07/27**
Update count: **0**

Registration date
2021-10-19, 1400/07/27

Registrant information

Name
Ali Amoushahi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 31 3667 6152

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-10-26, 1400/08/04

Expected recruitment end date
2021-11-25, 1400/09/04

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Efficacy and safety of Ethanol inhalation on early stage of COVID-19 (a clinical trial study)

Public title
Inhalation Ethanol therapy in COVID-19
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Positive RT-PCR test of SARS-COV2 Less than 7 days of starting of signs or symptoms of COVID-19 Age 15-69 yr
Exclusion criteria:
Pregnancy History of Asthma History of Alcohol dependency History of Seizure Contraindication of Ethanol addministration Disagreement of patient physician
Age
From **15 years** old to **69 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size
Target sample size: **86**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization method: Simple randomization Randomization tool: Random number table Even and zero digits are assigned to the ethanol treatment group and odd numbers to the control group.
Blinding (investigator's opinion)
Triple blinded
Blinding description
The blinding of the participant is done by not telling him the name of the drug under study. Analysts and staff collecting the data are given questionnaires in two groups named A and B.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committees of School of Medicine - Isfahan University of Medical Sciences
Street address
Isfahan University of Medical Sciences,Isfahan,Iran
City
Isfahan
Province
Isfehan
Postal code
81746-73461
Approval date
2021-09-25, 1400/07/03
Ethics committee reference number
IR.MUI.MED.REC.1400.506

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
Requires non-temporary hospitalization
Timepoint
Daily until 5 daus
Method of measurement
Counting the days

2

Description
Needing to ICU admission
Timepoint
Days 7, 14, 21
Method of measurement
Evaluate medical file records

3

Description
Mortality Rate
Timepoint
Days 7, 14, 21, 28
Method of measurement
Evaluate medical file records

4

Description
Respiratory status of patients
Timepoint
Days from 1 to 5
Method of measurement
SPO2

5

Description

Inflammatory condition

Timepoint

Days 1-5-14

Method of measurement

WBC counting -CRP titration

6

Description

Clinical status

Timepoint

Days 1-5-14

Method of measurement

Score from the table of clinical signs

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this group, in addition to the current treatment of Covid-19, which is remdesivir and methylprednisolone or dexamethasone, nebulizing ethanol is also added in this way. Four times a day, each time 10 ml of ethanol 70% of Sepahan bio-product CO. is poured in oxygen flowmeter or in the tank of the nebulizer device. After that, we add 10 ml of distilled water to it and encourage the patient to inhale it from mouth and nose. This technique must repeat for five days.

Category

Treatment - Drugs

2

Description

Control group: In this group, the current treatment of Covid-19, which is remdesivir and methylprednisolone or dexamethasone, is continued, and 20 ml of distilled water as placebo is poured into an oxygen flow meter or nebulizer, and the patient is encouraged to inhale it.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Isa Ben Maryam Hospital

Full name of responsible person

Ali Amoushahi

Street address

Shams Abadi St.

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Isfahan

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8134735945

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aliamoushah@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghju Javanmard

Street address

Hezar Jarib Ave.

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Email

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Web page address

https://research.mui.ac.ir/

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Elham Moazam

Position

Social medicine specialist

Latest degree

Specialist
Other areas of specialty/work
Public Health/Community Medicine
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Person responsible for scientific inquiries

Contact
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Ali Amoushahi
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Person responsible for updating data

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Latest degree
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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All data is shareable.
When the data will become available and for how long
Access period starts 6 months after the results are published.
To whom data/document is available
It will be available only to researchers working in academic and scientific institutions.
Under which criteria data/document could be used
It is permissible to use this data to find patients who respond better to this treatment.
From where data/document is obtainable
Contact Ali Amoshahi by phone (00989131158298) or email (aliamoushah@gmail.com).
What processes are involved for a request to access data/document
The request will be answered in a week in consultation with other partners in the project.
Comments