

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Aug 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)

Phone

+98 31 3667 6152

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aliamoushahi@mail.mui.ac.ir

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 administration 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

Isfahan

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 days

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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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
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Fax
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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
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Person responsible for updating data

Contact

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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 Amoushahi 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