

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jun 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

##### Email address

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.

##### **City**

Isfahan

##### **Province**

Isfahan

##### **Postal code**

8134735945

##### **Phone**

+98 31 3235 1541

##### **Email**

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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##### **Fax**

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##### **Email**

research@mui.ac.ir

##### **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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Specialist physician  
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Specialist  
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Anesthesiology  
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aliamoushah@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Esfahan University of Medical Sciences  
**Full name of responsible person**  
Ali Amoushahi  
**Position**  
Specialist Physician  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
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**Street address**  
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aliamoushah@gmail.com

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Esfahan University of Medical Sciences  
**Full name of responsible person**  
Ali Amoushahi  
**Position**

## 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