

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 2026

### Double blind clinical trial study on Evaluation of the effectiveness of Ipecac homeopathic remedy in control of Clinical manifestations of COVID-19

#### Protocol summary

##### Study aim

Evaluation of the efficacy of Ipecac homeopathy remedy in controlling covid-19 disease symptoms and accelerating the recovery process

##### Design

A randomized, controlled, double-blind, placebo-controlled clinical trial

##### Settings and conduct

Patients with covid19 admitted to rasoul-e-Akram and Firoozgar Hospitals are included in the study. Both patient and therapist are blinded

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients admitted with suspicious or definite diagnosis of Covid-19(according to national guideline). Definition of Covid-19 Suspected Case: A. Patient with respiratory symptoms with radiologic manifestations of unilateral or bilateral multilobular infiltration on CT scan or chest x-ray B- Pneumoniae person who despite the appropriate treatments, has poor clinical response and in an unusual and unexpected way the patient's clinical condition becomes more acute and aggravated. Exclusion criteria: • Patients who are treated with corticosteroids or immunosuppressants for any reason. • Patients who cannot take oral medication due to decreased consciousness.

##### Intervention groups

Ipecac homeopathy remedy is prescribed with dose of 15 drops every 2 hours for 6 hours and then 15 drops every 6 hours for 3 days.

##### Main outcome variables

Fever; Cough; Shortness of breath; Chills; Myalgia; O2 Saturation; Number of days admitted; Number of lymphocytes; Serum CRP level; Ventilator requirement; Oxygen intake and rout of its use and finally side effect of urticaria, itching and eruption.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20140907019073N4**

Registration date: **2020-03-29, 1399/01/10**

Registration timing: **prospective**

Last update: **2020-03-29, 1399/01/10**

Update count: **0**

##### Registration date

2020-03-29, 1399/01/10

##### Registrant information

##### Name

Ali Mazaherinezhad

##### Name of organization / entity

IUMS

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6435 2446

##### Email address

mazaherinezhad.a@iums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-04-03, 1399/01/15

##### Expected recruitment end date

2020-07-05, 1399/04/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

Double blind clinical trial study on Evaluation of the effectiveness of Ipecac homeopathic remedy in control of Clinical manifestations of COVID-19

### Public title

Evaluation of the effectiveness of Ipecac homeopathic remedy in control of Clinical manifestations of COVID-19

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Suspected or uncertain cases of patients admitted to one of Rasoul-e-Akram or Firoozgar Hospitals with a diagnosis of Covid19 (based on national Guideline).

#### Exclusion criteria:

Patients should not be intubated. Patient should not be immune defective.

### Age

No age limit

### Gender

Both

### Phase

3

### Groups that have been masked

- Participant
- Care provider
- Outcome assessor

### Sample size

Target sample size: 60

### Randomization (investigator's opinion)

Randomized

### Randomization description

Firstly patients are divided into moderate and severe groups to match the severity of the disease then according to computerized block randomization division is performed.

### Blinding (investigator's opinion)

Double blinded

### Blinding description

Bottles are numbered in each group and finally according to computerized block randomization division is performed , the remedies and placebo put on the numbered bottles by one of researchers who is only person that know about this concealment. Every patient admitted to the ward and who wants to participate this survey take this bottles respectively. Patients, therapist and evaluator does not know the true contents of the bottles(which have equal taste and odor) and the study is double-blinded.

### Placebo

Used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Iran University of Medical Sciences

##### Street address

Iran University of Medical sciences, south side of Hemmat highway, Tehran, Iran.

##### City

Tehran

##### Province

Tehran

##### Postal code

1449614535

#### Approval date

2020-03-26, 1399/01/07

#### Ethics committee reference number

IR.IUMS.REC.1399.039

## Health conditions studied

### 1

#### Description of health condition studied

covid-19

#### ICD-10 code

U07.1

#### ICD-10 code description

Covid-19

## Primary outcomes

### 1

#### Description

fever

#### Timepoint

The first day, the second day, the third day

#### Method of measurement

Check body temperature with thermometer

### 2

#### Description

Cough

#### Timepoint

The first day, the second day, the third day

#### Method of measurement

Physician report

### 3

#### Description

Shortness of breath

#### Timepoint

The first day, the second day, the third day

#### Method of measurement

Patient Report

## 4

### **Description**

Chills

### **Timepoint**

The first day, the second day, the third day

### **Method of measurement**

Patient Report

## 5

### **Description**

Myalgia

### **Timepoint**

The first day, the second day, the third day

### **Method of measurement**

Patient Report

## 6

### **Description**

O2 arterial blood saturation

### **Timepoint**

The first day, the second day, the third day

### **Method of measurement**

Pulse Oximeter Report

## 7

### **Description**

Number of lymphocytes

### **Timepoint**

The first day, the second day, the third day

### **Method of measurement**

Blood test

## 8

### **Description**

Serum CRP

### **Timepoint**

The first day, the second day, the third day

### **Method of measurement**

Blood test

## **Secondary outcomes**

### 1

#### **Description**

Need ventilator

#### **Timepoint**

The first day, the second day, the third day

#### **Method of measurement**

Physician diagnosis

### 2

#### **Description**

The amount of oxygen received

#### **Timepoint**

The first day, the second day, the third day

#### **Method of measurement**

Manometer view

### 3

#### **Description**

Oxygen Intake Method

#### **Timepoint**

The first day, the second day, the third day

#### **Method of measurement**

Observation

## **Intervention groups**

### 1

#### **Description**

The one globule of (Ipecac)homeopathy remedy with C30 potency produced by Hellios homeopathy pharmacy distilled in 20 ml. 10 degree alcohol which will be administered at a dose of 15 drops every 2 hours for 6 hours and then every 6hours at 15 drops for 3 days.

#### **Category**

Treatment - Drugs

### 2

#### **Description**

The one placebo(Sac-lac) distilled in 20 ml. 10 degree alcohol which will be administered at a dose of 15 drops every 2 hours for 6 hours and then 15 drops every 6 hours for 3 days. remedy and placebo have both common bases and are similar in taste, color, odor and taste.

#### **Category**

Placebo

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Rasoul-e- Akram hospital

##### **Full name of responsible person**

Ali Mazaherinezhad

##### **Street address**

Niayesh St, Satarkhan Av

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

1449614535

##### **Phone**

+98 21 6650 2248

##### **Fax**

+98 21 6650 2248

##### **Email**

hrmc@iums.ac.ir

## 2

### Recruitment center

**Name of recruitment center**

Firoozgar Hospital

**Full name of responsible person**

Ali Mazaherinezhad

**Street address**

Beh Afarin Street , Karim Khan Ave, Valiasr Square

**City**

Tehran

**Province**

Tehran

**Postal code**

1593748711

**Phone**

+98 21 8214 1600

**Fax****Email**

h\_firoozgar@yahoo.com

### Sponsors / Funding sources

## 1

### Sponsor

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Professor A.Motevalian

**Street address**

Iran University of Medical sciences, south side of Hemmat highway, Tehran, Iran.

**City**

Tehran

**Province**

Tehran

**Postal code**

1449614535

**Phone**

+98 21 8670 2504

**Fax**

+98 21 8670 2503

**Email**

motevalian.a@iums.ac.ir

**Web page address**

<https://vcr.iums.ac.ir/>

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Iran 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**

Medical Council of Iran

**Full name of responsible person**

Farbod Rahnama Chitsaz

**Position**

Consultant

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Homeopathy

**Street address**

No. 119 Shahid Farshi Moqaddam street(16th)

**City**

Tehran

**Province**

Tehran

**Postal code**

1439837953

**Phone**

+98 21 8413 0001

**Email**

farbod.chitsaz@gmail.com

### Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Ali Mazaherinezhad

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Sport Medicine

**Street address**

Hemat Highway next to Milad Tower. Iran University of Medical Sciences

**City**

Tehran

**Province**

Tehran

**Postal code**

۱۴۴۹۶۱۴۵۳۵

**Phone**

+98 21 86701

**Email**

Mazaheri.a@iums.ac.ir

### Person responsible for updating data

**Contact****Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Somaye Mahroozade

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Traditional Medicine

**Street address**

No. 847 Vadat Eslami Street

**City**

Tehran

**Province**

Tehran

**Postal code**

۱۱۱۴۷۳۳۳۱۱

**Phone**

+98 21 5563 9667

**Email**

dr.mahroozade@gmail.com

**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**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available

**Title and more details about the data/document**

IPD collection for the primary and secondary outcomes

**When the data will become available and for how long**

immediately after publication

**To whom data/document is available**

people working in academic institution

**Under which criteria data/document could be used**

The result of further analysis may not be presented to public without permission

**From where data/document is obtainable**

mazaheri.a@iums.ac.ir mazaherinezhad@gmail.com

mahroozade.a@iums.ac.ir

**What processes are involved for a request to access data/document**

A reasonable request from an academic source will be responded within 14 working days

**Comments**