

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jul 2026

### Evaluation of the effect of adding ivermectin to standard therapies on the outcome of intubated Covid-19 patients under ventilator

#### Protocol summary

##### Study aim

The goal of this study was to evaluate the effect of adding ivermectin to standard treatments on the outcome of intubated patients under 19-ventilator.

##### Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 per 100 patients. Random Allocation Software will be used to randomize the random block method

##### Settings and conduct

Intubated patients in COVID-ICU , Ahvaz hospitals, after entering the study, are placed in one of two groups receiving ivermectin or control. Patients become blind due not know the type of gavage drug.

##### Participants/Inclusion and exclusion criteria

All patients who have been admitted to COVID-ICU and have been intubated will be admitted to the study if they meet the conditions for admission and sign a written informed consent form from the patient's relatives. Inclusion criteria: Covid 19 PCR test, intubated patient, no increase in liver enzymes, at least 18 years old. Exclusion criteria: history of drug allergy, pregnant women, patient's refusal to continue participating in the study

##### Intervention groups

In addition to receiving the drugs prescribed in accordance with the national protocol, ivermectin for patients in the intervention group is started and continues for 5 days from the time the patient enters the intensive care unit (the first day 6 mg twice a day and the second day until Fifth 3 mg twice a day) In the placebo group, they receive standard treatment with starch gavage

##### Main outcome variables

30 days Mortality

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190417043295N2**  
Registration date: **2021-09-20, 1400/06/29**  
Registration timing: **prospective**

Last update: **2021-09-20, 1400/06/29**

Update count: **0**

##### Registration date

2021-09-20, 1400/06/29

##### Registrant information

##### Name

Reza Baghbanian

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 61 3222 0168

##### Email address

baghbanian-r@ajums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-09-23, 1400/07/01

##### Expected recruitment end date

2022-01-20, 1400/10/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of the effect of adding ivermectin to standard therapies on the outcome of intubated Covid-19 patients under ventilator

## Public title

Evaluation of the effect of ivermectin in intubated patients 19

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Covid PCR test 19 positive Intubated patient No increase in liver enzymes

### Exclusion criteria:

History of drug allergy Pregnant Women Withdrawal of the patient's family from continuing to participate in the study

## Age

From 18 years old

## Gender

Both

## Phase

3

## Groups that have been masked

- Participant
- Data analyser

## Sample size

Target sample size: 40

## Randomization (investigator's opinion)

Randomized

## Randomization description

Randomization method : Block randomization with blocks with size 4, Randomization unit: Individual, Randomization tool: Random, Allocation Software How to make a random sequence: Random sequence is generated using the software, Hide method: (allocation concealment) The matte envelope method is used to hide the random sequence

## Blinding (investigator's opinion)

Double blinded

## Blinding description

The patient is not conscious due to the condition and does not know the type of medication received and the statistical analyzer will analyze the information under the headings of groups A and B and will be unaware of which group received which medication.

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Ahvaz jundishapur University of Medical Sciences

## Street address

Azadegan street, Imam khomeini Hospital

## City

Ahvaz

## Province

Khuzestan

## Postal code

61936673111

## Approval date

2021-07-04, 1400/04/13

## Ethics committee reference number

IR.AJUMS.REC.1400.234

## Health conditions studied

### 1

#### Description of health condition studied

COVID-19, virus not identified

#### ICD-10 code

U07.2

#### ICD-10 code description

COVID-19, virus not identified

## Primary outcomes

### 1

#### Description

mortality rate

#### Timepoint

30 days range, Daily from the time the patient enters the study

#### Method of measurement

Vital sign check in 30 days range

## Secondary outcomes

### 1

#### Description

intubation period

#### Timepoint

in 30 day range, Daily from the time the patient enters the study

#### Method of measurement

Visual Observation

### 2

#### Description

Lung Compliance

#### Timepoint

Daily from the time the patient enters the study

#### Method of measurement

Calculated based on ventilator data

## Intervention groups

## 1

### Description

Intervention group: In addition to the drugs prescribed according to the national protocol, Receiving Ivermectin, 6 mg twice daily on the first day and 3 mg twice daily on the second to fifth day, Gavage every 12 hours, 6 mg tablet (Alborz Daru)

### Category

Treatment - Drugs

## 2

### Description

Control group: In addition to the drugs prescribed according to the national protocol, placebo is taken orally in the form of a drug similar to ivermectin (starch tablets), By gavage every 12 hours, the equivalent volume of the ivermectin group for 5 days

### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Ahvaz Imam Khomeini Hospital

##### Full name of responsible person

Dr. Reza Baghbanian

##### Street address

24 metery street, east sahely highway, ahvaz

##### City

Ahvaz

##### Province

Khouzestan

##### Postal code

6193673111

##### Phone

+98 61 3292 3985

##### Email

Baghbanian.r@ajums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Ahvaz University of Medical Sciences

##### Full name of responsible person

Mehdi Ahmadi moghadam

##### Street address

24 metery street, East sahely highway, Ahvaz

##### City

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##### Province

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##### Email

Baghbanian.r@ajums.ac.ir

##### Web page address

<http://vchresearch.ajums.ac.ir/fa-IR/vchresearch.ajums.ac/4937/page/%D8%B5%D9%81%D8%AD%D9%87-%D8%A7%D8%B5%D9%84%DB%8C-%D9%85%D8%B9%D8%A7%D9%88%D9%86%D8%A>  
A

##### Grant name

Pain and anesthesia research center

##### Grant code / Reference number

PAIN-0004

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

Yes

##### Title of funding source

Ahvaz 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

Ahvaz University of Medical Sciences

##### Full name of responsible person

Reza Baghbanian

##### Position

assistant professor

##### Latest degree

Specialist

##### Other areas of specialty/work

Anesthesiology

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24 metery street, east sahely highway, ahvaz

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##### Province

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## Person responsible for scientific inquiries

#### Contact

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**Email**

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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**

No - There is not 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