

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Aug 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

Khouzestan

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

Ahvaz

Province

Khouzestan

Postal code

6193673111

Phone

+98 61 3292 3985

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>

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

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

Person responsible for scientific 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

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

Person responsible for updating data**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

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

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