Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Nov 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
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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
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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%AA
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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Person responsible for updating data

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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