Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jul 2026

Comparison of the effect of adding nebulized low molecular weight heparin to the treatment of patients with Covid 19 who are treated with Remdesivir on an outpatient basis compared to the usual treatment during five days

Protocol summary

Study aim
Determination and clinical effectiveness of low molecular weight heparin on lung inflammation and acute respiratory syndrome was done.

Design
Clinical trial with control group, double blind, randomized, phase 3 on 42 patients. SPSS version 25 was used for randomization.

Settings and conduct
The study is double-blind. The patients and the person analyzing the study results will not know about the treatment groups.Patients referred to Razi Ahvaz Hospital are divided into two equal groups and the peak expiratory flow rate is measured by Peak flowmeter, and the vital signs of the patients are also measured and recorded, then the appropriate dose of Remdesivir and the appropriate dose of low molecular weight heparin (0.5 mg per kilogram) are given to one of the groups and the other group will be given the appropriate dose of Remdesivir and nebulized distilled water for 5 days on an outpatient basis.

Participants/Inclusion and exclusion criteria
Inclusion criteria:patients with a diagnosis of covid-19, who have clinical and paraclinical criteria, and with symptoms of shortness of breath. Exclusion criteria: Patients with poor general condition and hospitalization in the emergency room and ICU, heart disease, acute medical problems, pregnant women, patients with suspicion of Pulmonary thromboembolism , kidney problems, coagulation problems, and drug sensitivity.

Intervention groups
The intervention group includes patients with Covid-19 who are subjected to the intervention of the appropriate dose of Remdesivir and the appropriate dose of low molecular weight heparin (0.5 mg per kilogram). The control group includes patients with Covid-19 who are treated with the appropriate dose of Remdesivir and nebulized distilled water.

Main outcome variables
Peak expiratory flow rate؛ respiratory rate; saturation O2

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20231008059655N1**
Registration date: **2023-11-06, 1402/08/15**
Registration timing: **prospective**

Last update: **2023-11-06, 1402/08/15**
Update count: **0**

Registration date
2023-11-06, 1402/08/15

Registrant information

Name
Ali Vefagh nematollahi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 61 3292 3985

Email address
shiri.t@ajums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-11-11, 1402/08/20

Expected recruitment end date

2023-12-21, 1402/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of adding nebulized low molecular weight heparin to the treatment of patients with Covid 19 who are treated with Remdesivir on an outpatient basis compared to the usual treatment during five days

Public title

The effect of adding nebulized low molecular weight heparin to the treatment of outpatients with Covid 19

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Positive Covid-19 test Patients who are treated on an outpatient basis

Exclusion criteria:

Patients with poor general condition and hospitalization in the emergency room Patients with acute medical problems

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **42**

Randomization (investigator's opinion)

Randomized

Randomization description

The participants are individually divided into two groups based on the 4-way random block permutation method and using SPSS version 25 software (version 25, IBM Corporation, Armonk, NY), which is allocation concealment by using sequentially numbered, opaque, sealed envelopes will be done in random order.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is a double-blind study. Participants will be divided into two groups of low molecular weight heparin nebulization and placebo nebulization, which is the same color and undetectable to the patient. In such a way that the person who administers the medicine in the two groups will be different from the person who examines the results of the interventions. The interventions are performed by the emergency nurse, but the peak flowmetry results are measured by an intern who is unaware of the intervention groups. Also, the patients and the person who analyzes the results of the study will not know about the treatment groups.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahvaz Jondishapur University of Medical Sciences

Street address

Ahvaz Jondishapur University of Medical Sciences, Esfand St, Farvardin Blvd, Ahvaz

City

Ahvaz

Province

Khouzestan

Postal code

6135715794

Approval date

2023-10-01, 1402/07/09

Ethics committee reference number

IR.AJUMS.REC.1402.322

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

Peak expiratory flow rate

Timepoint

In this study, the time periods of measuring the peak expiratory flow rate will be measured on days 1, 2, 3, 4 and 5 after receiving the drug.

Method of measurement

Peak flow meter

2

Description

saturation O2

Timepoint
In this study, the time periods of measuring oxygen saturation are measured on days 1, 2, 3, 4 and 5 after receiving the drug.
Method of measurement
Pulse oximeter

Secondary outcomes

1

Description
Respiratory rate
Timepoint
In this study, the time periods of measuring respiratory rate are measured on days 1, 2, 3, 4 and 5 after receiving the drug.
Method of measurement
Number of breaths per minute

2

Description
Pulse rate
Timepoint
In this study, the time periods of measuring pulse rate are measured on days 1, 2, 3, 4 and 5 after receiving the drug.
Method of measurement
The number of heartbeats per minute

Intervention groups

1

Description
Intervention group:Patients with covid 19 are treated with the appropriate dose of remdesivir (Ronak Pharmaceutical Company) (The first day with a dose of 200 mg and the second, third, fourth and fifth day with doses of 100 mg) and the appropriate dose of nebulized low molecular weight heparin (Ronak Pharmaceutical Company) (0.5 mg per kg) at the same time as receiving Remdesivir for five days. Then every day after taking the drugs, the patient's peak expiratory flow rate is recorded by the peak flowmeter and the patient's vital signs are also recorded. The person who administers the medicine in the two groups will be different from the person who examines the results of the interventions. The interventions are performed by the emergency nurse, but the peak flowmetry results are measured by an intern who is unaware of the intervention groups. Also, the patients and the person who analyzes the results of the study will not know about the treatment groups.
Category
Treatment - Drugs

2

Description
Control group: Patients with covid 19 are treated with the appropriate dose of Remdesivir (Ronak Pharmaceutical Company) (The first day with a dose of 200 mg and the second, third, fourth and fifth day with doses of 100 mg) and the appropriate dose of nebulized distilled water (0.5 mg per kg) at the same time as receiving Remdesivir for five days. Then every day after taking the drugs, the patient's peak expiratory flow rate is recorded by the peak flowmeter and the patient's vital signs are also recorded.The person who administers the medicine in the two groups will be different from the person who examines the results of the interventions. The interventions are performed by the emergency nurse, but the peak flowmetry results are measured by an intern who is unaware of the intervention groups. Also, the patients and the person who analyzes the results of the study will not know about the treatment groups.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Razi hospital
Full name of responsible person
Ali Vefagh nematollahi
Street address
Razi Hospital, Palestine St., Ahvaz
City
Ahvaz
Province
Khouzestan
Postal code
6133633366
Phone
+98 61 3333 6513
Email
shiri.t@ajums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Ali Vefagh nematollahi
Street address
Emergency Medicine Department, Imam Khomeini Hospital, Azadegan St, Ahvaz
City
Ahvaz
Province
Khouzestan
Postal code
6193673166
Phone
+98 61 3292 3985
Email
Shiri.t@ajums.ac.ir

Grant name
Grant code / Reference number
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
Ali Vefagh nematollahi
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
Emergency Medicine
Street address
Emergency Medicine Department, Imam Khomeini Hospital, Azadegan St, Ahvaz
City
Ahvaz
Province
Khouzestan
Postal code
6193673166
Phone
+98 61 3292 3985
Email
Shiri.t@ajums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Ali Vefagh nematollahi
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
Emergency Medicine
Street address
Emergency Medicine Department, Imam Khomeini Hospital, Azadegan St, Ahvaz
City
Ahvaz
Province
Khouzestan
Postal code
6193673166
Phone
+98 61 3292 3985
Fax
Email
Shiri.t@ajums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Ali Vefagh nematollahi
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
Emergency Medicine
Street address
Emergency Medicine Department, Imam Khomeini Hospital, Azadegan St, Ahvaz
City
Ahvaz
Province
Khouzestan
Postal code
6193673166
Phone
+98 61 3292 3985
Fax
Email
Shiri.t@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
Undecided - It is not yet known if there will be 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
Not applicable
Data Dictionary
Not applicable