Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Jul 2026

The Evaluation of effectiveness of heparin nebulizer in reduction of respiratory distress in patients with COVID-19

Protocol summary

Study aim
The Evaluation of effectiveness of heparin nebulizer in reduction of respiratory distress in patients with COVID-19

Design
This study is a one-blind randomized clinical trial, without control group, with 2 intervention parallel groups and phase 2-3, in which 64 patients are randomly divided into 2 groups of 30 using a random number table.

Settings and conduct
main outcome variables will be studied before the intervention. Patients will be intervened for three days and after three days the main outcome variables in the two groups will be re-evaluated and the results will be recorded in the two groups. And will be compared. This study is performed in Shohada Kargar and Shahid Sadoughi hospitals in Yazd.

Participants/Inclusion and exclusion criteria
Inclusion criteria: All patients with COVID-19 treated in Yazd in the summer of 1400 with lung involvement proven on radiography and with respiratory distress. Patients treated with anticoagulants, patients with Types of coagulation disorders, Patients with proven cardiovascular disease, Patients taking medications that interfere with the medications we are using.

Intervention groups
total of 60 patients selected by simple random sampling using a random number table will be divided into two groups of 30: intervention and placebo. Then, 60 questionnaires were prepared in advance, 30 of which were written in group A and the other 30 in group B. Is provided to the patient and The patient is asked to choose one of them blindly. If he chooses A, he will receive a 5,000-unit heparin nebulizer every 8 hours, and if he chooses B, he will be given the same amount of normal saline.

Main outcome variables
Respiratory rate, severity of lung involvement on radiograph, percentage of arterial blood oxygen saturation, patient body temperature and severity of shortness of breath

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210513051275N1**
Registration date: **2021-07-06, 1400/04/15**
Registration timing: **prospective**

Last update: **2021-07-06, 1400/04/15**
Update count: **0**

Registration date
2021-07-06, 1400/04/15

Registrant information

Name
Maryam Tavakoli

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 35 3825 4040

Email address
m.tavakoli@iayazd.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-08-06, 1400/05/15

Expected recruitment end date
2021-09-06, 1400/06/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The Evaluation of effectiveness of heparin nebulizer in reduction of respiratory distress in patients with COVID-19

Public title
The Evaluation of effectiveness of heparin nebulizer in reduction of respiratory distress in patients with COVID-19

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
All patients with COVID-19 treated in Yazd In the Summer of 2021, which was proven by radiographic involvement in radiography andThey have respiratory distress and O2 SAT below 90%.

Exclusion criteria:
Patients treated with anticoagulants Patients with a variety of coagulation disorders Patients who have impaired coagulation tests at initial evaluation. Patients with proven cardiovascular disease Patients taking medications that interfere with the medications we use. Patients with severe COVID-19 who require ICU admission and mechanical ventilation prior to intervention. Patients who do not have clear lung involvement on radiography and respiratory distress.

Age
No age limit

Gender
Both

Phase
2-3

Groups that have been masked

- Participant

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
60 patients selected by simple random sampling and Using a table of random numbers, they will be divided into two groups of 30 intervention and placebo. Then, 60 questionnaires were prepared in advance, on 30 of which were group A and It is written on the other 30 numbers of group B. It is given to the patient and the patient is asked to choose one of them blindly. If he chooses A, he will receive a heparin nebulizer and If B is selected, the same amount of normal saline will be nebulized for it.

Blinding (investigator's opinion)
Single blinded

Blinding description
En Only patients are unaware of how to group and the amount and type of medication used It is necessary to mention in this research the drugs used and Their levels in both experimental groups are completely routine and tested

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Tehran Islamic Azad University of Medical Sciences

Street address
No: 403, Corner of Gol Yakh St., Aineh Blvd., Amir Paberja St., Gholhak Intersection, Dr.Shariati St.

City
Tehran

Province
Tehran

Postal code
1916893813

Approval date
2021-04-10, 1400/01/21

Ethics committee reference number
IR.IAU.PS.REC.1400.002

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
Number of breaths

Timepoint
Before the intervention and three days after the start of the intervention

Method of measurement
Cardiac device for monitoring and recording information in a questionnaire

2

Description
Percentage of arterial blood oxygen saturation (SpO2)

Timepoint
Before the intervention and three days after the start of the intervention

Method of measurement
Pulse oximetry of cardiac monitoring device and recording information in a questionnaire

3

Description
Patient body temperature
Timepoint
Before the intervention and three days after the start of the intervention
Method of measurement
Digital thermometer (forehead temperature measurement)

4

Description
Severity of lung involvement
Timepoint
Before the intervention and three days after the start of the intervention
Method of measurement
Radiographic device

5

Description
Severe shortness of breath
Timepoint
Before the intervention and three days after the start of the intervention
Method of measurement
Patient self-declaration

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: They will be treated with a heparin nebulizer at a dose of 5,000 units every 8 hours
Category
Treatment - Drugs

2

Description
Intervention group: They will be treated with normal saline (placebo) at a dose of 5,000 units every 8 hours
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Sadoughi Hospital, Yazd
Full name of responsible person
Dr. Maryam Tvakoli
Street address
Ibn Sina Street, Shahid Ghandi Boulevard, Safaieh
City
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Province
Yazd
Postal code
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Phone
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Fax
+98 35 3822 4100
Email
sadoghi-hospital@ssu.ac.ir
Web page address
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2

Recruitment center
Name of recruitment center
Yazd Shohada Kargar Hospital
Full name of responsible person
Dr. Maryam Tvakoli
Street address
Prayer Square, Modares Bolvd
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Yazd
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Yazd
Postal code
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Phone
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Fax
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shohadakargar.hos@tamin.ir
Web page address
https://shohadakargar.tamin.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Dr Seyed Mohammadreza Mortazavi Zade
Street address
Boulevard of the Shohadaie Gomnam, Safaieh
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Yazd
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Phone

+98 35 3187 2200

Fax

+98 35 3821 5034

Email

info@iauyazd.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Islamic Azad University

Proportion provided by this source

100

Public or private sector

Private

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

Islamic Azad University

Full name of responsible person

Ḍr.Maryam Tavakoli

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Internal Medicine

Street address

Shohada kargar hospital, Modares blvd, Yazd

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Ḍr.Maryam Tavakoli

Position

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Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Ḍr.Maryam Tavakoli

Position

Associate professor

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Other areas of specialty/work

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Web page address

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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

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

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