

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

Comparison of enoxaparin effects with prophylactic or therapeutic dosage on overall survival in severe COVID-19 patients

Protocol summary

Study aim

The current study is aimed to investigate and compare potential effects of different doses of enoxaparin treatment in patients with severe COVID-19.

Design

Two arm parallel group superiority trial, non-blinded, phase 3. Patients were block randomized in a 1:1 ratio using SPSS software.

Settings and conduct

Severe Covid-19 patients were treated with the respective doses (based on allocated groups) of enoxaparin until discharge or death. Participants and investigators were not blinded.

Participants/Inclusion and exclusion criteria

Patients over 18 years of age with an RT-PCR confirmed COVID-19 diagnosis and severe clinical presentations who required hospitalization were eligible for inclusion if they had D-dimer levels of more than four times the normal upper limit. Severe COVID-19 presentation was defined as the presence of two of the following: (1) respiratory rate over 30 times/minute, (2) Spo2 of less than 93%, (3) Pao2/Fio2 less than 300 mmHg, (4) rapid progression (>50%) on CT-scan over 24-48 hours (10). Exclusion criteria included pregnancy, history of CVA in the last month, history of major surgery in the last two weeks, history of heparin-induced thrombocytopenia, other definitive indications for therapeutic anti-coagulant treatment, and definitive enoxaparin contraindications.

Intervention groups

Intervention group: Enoxaparin with therapeutic dose
Control group: Enoxaparin with prophylactic dose

Main outcome variables

All case mortality and overall survival

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220412054515N1**

Registration date: **2022-05-04, 1401/02/14**

Registration timing: **prospective**

Last update: **2022-05-04, 1401/02/14**

Update count: **0**

Registration date

2022-05-04, 1401/02/14

Registrant information

Name

Mohamadreza Fattahi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6656 4517

Email address

mr-fattahi@alumnus.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-15, 1401/02/25

Expected recruitment end date

2022-08-30, 1401/06/08

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of enoxaparin effects with prophylactic or therapeutic dosage on overall survival in severe COVID-19 patients

Public title

Prophylactic vs. therapeutic enoxaparin in severe COVID-19

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
COVID-19 infection diagnosed by PCR Hospitalization requirement Having at least two signs of severe COVID-19 infection: (1) respiratory rate>30 (2) Spo2<93% (3) Pao2/Fio2<300 (4) progression in CT scan imaging>50% in 48 hours
Exclusion criteria:
Pregnancy History of CVA in last month History of major surgery in last two weeks History of heparin induced thrombocytopenia Other definitive indications for therapeutic enoxaparin treatment Any contraindication for enoxaparin treatment

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **220**

Randomization (investigator's opinion)
Randomized

Randomization description
Individual patients were randomized in a 1:1 ratio, using block randomization with a computer-generated random allocation algorithm. allocations were concealed until randomization.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of Sina Hospital
Street address
Sina Hospital, Hassan-Abad square, Tehran
City
Tehran
Province
Tehran
Postal code
1136746911

Approval date
2022-05-01, 1401/02/11
Ethics committee reference number
IR.TUMS.SINAHOSPITAL.REC.1401.013

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
Cumulative 6-month survival
Timepoint
6 months after admission
Method of measurement
Visit or phonecall

Secondary outcomes

1

Description
Hospitalization duration (days)
Timepoint
After discharge or death
Method of measurement
Patient files

2

Description
Need for Intensive Care Unit admission
Timepoint
After discharge or death
Method of measurement
Patient files

3

Description
Need for mechanical ventilation
Timepoint
After discharge or death of patient
Method of measurement
Patient files

4

Description
Major bleeding defined by International Society on Thrombosis and Haemostasis criteria
Timepoint

After discharge or death
Method of measurement
Patient files

Intervention groups

1

Description

Intervention group: Therapeutic dose enoxaparin group: subcutaneous injections of enoxaparin, 1 mg/Kg, Twice a day, Tehran Chemie Co., if patients had a GFR lower than 30 mL/min injections were administered only once a day

Category

Treatment - Drugs

2

Description

Control group: Prophylactic dose enoxaparin group: subcutaneous injections of enoxaparin, 40 mg, once a day, Tehran Chemie Co., if patients had a GFR lower than 30 mL/min, 30 mg dose was used, in cases of a BMI greater than 40 injections were administered twice a day.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina hospital

Full name of responsible person

Mohammadreza Fattahi

Street address

Sina Hospital, Imam-Khomeini street, Hassan-Abad square

City

Tehran

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Tehran

Postal code

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Email

hosp_sina@sina.tums.ac.ir

Web page address

<https://sinahospital.tums.ac.ir/detail.aspx?content=contact>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Akbar Fotuhi

Street address

Research and technology division, 6th floor, Tehran University of Medical Sciences building, intersection of Keshavarz blvd. and Qods street

City

Tehran

Province

Tehran

Postal code

1417653761

Phone

+98 21 8163 3686

Email

vcr@tums.ac.ir

Web page address

<https://vcr.tums.ac.ir/>

Grant name

No Grant

Grant code / Reference number

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

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Mohammadreza Fattahi

Position

Research assistant

Latest degree

Medical doctor

Other areas of specialty/work

Virology

Street address

Sina Hospital, Imam-Khomeini street, Hassan-Abad square

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

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Position

Research assistant

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Medical doctor

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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

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammadreza Fattahi