

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Comparison of Two Dosing Nomograms of Heparin in Patients with Acute Coronary Syndrome (ACS) Hospitalized in the Cardiac Care Unit (CCU)

Protocol summary

Summary

The aim of this study is to compare two prevalent dosing nomograms of unfractionated heparin. Patients with acute coronary syndrome (ACS) hospitalized in the Cardiac Care Unit (CCU) of two university affiliated hospitals will be enrolled. Inclusion criteria are age >18 years, ACS, admission to CCU and exclusion criteria are receiving thrombolytic drugs in the past week, current bleeding, history of thrombocytopenia with heparin, receiving heparin prior to hospitalization, and thrombocytopenia. The first person that is admitted to the study randomly receives an even or odd number. Afterward, each subject gets either an odd or even number, consecutively. Patients with even number will be allocated in group 1 and individuals with odd number will receive heparin based on nomogram 2. This will be continued until number of patients in each group will be at least 70. Prior to commencing heparin infusion, aPTT and platelets are measured. Heparin will be given based on one of the nomograms and aPTT is controlled every 6 hours for at least 48 hours. Group 1 receives a bolus of 80 U/Kg/hr and an initial infusion rate of 17 U/Kg/hr. In the second group, a bolus of 60 U/Kg (maximum 4000 U) and an initial infusion rate of 12 U/Kg/hr (maximum 900U/hr) is given. Then, every 6 hours, rate of heparin will be changed based on aPTT results and the nomogram. Primary outcome is reaching therapeutic aPTT (46-70 s), and secondary outcomes are time to reach therapeutic aPTT and number of adjustments in the rate of heparin.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138708111221N2**

Registration date: **2011-07-12, 1390/04/21**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-07-12, 1390/04/21

Registrant information

Name

Mahdieh Namayandeh

Name of organization / entity

Shahid Sadoughi University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 35 1523 1421

Email address

hrc@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahid Sadoughi University of Medical Sciences

Expected recruitment start date

2010-01-01, 1388/10/11

Expected recruitment end date

2010-12-01, 1389/09/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Two Dosing Nomograms of Heparin in Patients with Acute Coronary Syndrome (ACS) Hospitalized in the Cardiac Care Unit (CCU)

Public title

Comparison of Two Dosing Nomograms of Heparin in Patients with Acute Coronary Syndrome (ACS) Hospitalized in the Cardiac Care Unit (CCU)

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: >18 years old; ACS; admission to CCU.

Exclusion criteria: receiving thrombolytic drugs in the past week; current bleeding; history of thrombocytopenia with heparin; receiving heparin prior to hospitalization; thrombocytopenic patients.

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 140

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shahid Sadoughi University of Medical Sciences

Street address

Shahid Sadooghi blvd

City

Yazd

Postal code

8916978477

Approval date

2006-02-16, 1384/11/27

Ethics committee reference number

42926

Health conditions studied

1

Description of health condition studied

acute coronay syndrome

ICD-10 code

I24.9

ICD-10 code description

Acute ischaemic heart disease, unspecified

Primary outcomes

1

Description

aPTT in the therapeutic range (46-70 s)

Timepoint

before infusion of heparin and every 6 hours until 48 hours after intervention

Method of measurement

standard methods of measuring aPTT

Secondary outcomes

1

Description

number of changes in the rate of heparin

Timepoint

every 6 hours until 48 hours after intervention

Method of measurement

observation

2

Description

time to reach therapeutic aPTT

Timepoint

every 6 hours until 48 hours after intervention

Method of measurement

measuring time by watch

Intervention groups

1

Description

Patients in group 1 receive a bolus of 80 U/Kg and an initial infusion rate of 17 U/Kg/hr. APTT is controlled every 6 hours for 48 hours. The therapeutic level of aPTT is 46-70 s. If aPTT is in this range, no intervention will be done. But if aPTT is 35-46 s, rate of infusion will be increased by 2 U/kg/hr and for aPTTs<35 s, rate will be raised by 4 U/kg/hr. If aPTT is 71-90 s or >90 s, the rate of heparin will be decreased by 2 or 3 U/kg/hr, respectively.

Category

Treatment - Drugs

2

Description

Patients in the second group receive a bolus of 60 U/Kg (maximum 4000 U) and an initial infusion rate of 12 U/Kg/hr (maximum 900U/hr). aPTT is measured every 6 hours up to 48 hours. For aPTT,46-70 s, no change in the rate will be done. But if aPTT is <46s, the rate will be increased by 2U/kg/hr. If aPTT is 71-80 s, 81-90 s, or >90 s, the rate of heparin will be decreased by 1, 2, or 3 U/kg/hr, respectively.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Yazd cardiovascular reaserch center

Full name of responsible person

Sedigheh Bagheri

Street address

Afshar hospital, Jomhoori blvd

City

Yazd

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Sadoughi University of Medical Sciences

Full name of responsible person

Tahereh Rahimdel

Street address

Shahid Sadooghi blvd

City

Yazd

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Sadoughi University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Yazd cardiovascular research center

Full name of responsible person

Roghieh Atashkooh

Position

Responsible of research services/diploma

Other areas of specialty/work

Street address

Afshar hospital, Jomhoori blvd

City

Yazd

Postal code

8917945556

Phone

+98 35 1523 1421

Fax

+98 35 1523 1421

Email

yazdheartcenter@gmail.com

Web page address

<http://www.ssu.ac.ir>

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Sadoughi University of Medical Sciences

Full name of responsible person

Moneyreh Modares Mosadegh

Position

lecturer/pharm.D

Other areas of specialty/work

Street address

Afshar hospital, Jomhoori blvd

City

Yazd

Postal code

8917945556

Phone

+98 35 1820 3419

Fax

+98 35 1820 3418

Email

mo_modares@yahoo.com

Web page address

<http://www.ssu.ac.ir>

Person responsible for updating data

Contact

Name of organization / entity

cardiovascular research center

Full name of responsible person

Mahdieh Namayandeh

Position

Reseach manager

Other areas of specialty/work

Street address

Jomhoori blvd

City

Yazd

Postal code

8917945556

Phone

+98 35 1523 1421

Fax

+98 35 1523 1421

Email

drnamayandeh@gmail.com

Web page address

<http://www.ssu.ac.ir>

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty