Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 unfractioned 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

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Mahdieh Namayandeh
Name of organization / entity
Shahid Sadoughi University of Medical Sciences
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Iran (Islamic Republic of)
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+98 35 1523 1421
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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 intevention
Method of measurement
observation

2

Description
time to reach therapeutic aPTT
Timepoint
every 6 hours until 48 hours after intevention
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 decresed 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

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Web page address
http://www.ssu.ac.ir

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
Resposible of research services/diploma

Other areas of specialty/work

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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