Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

Comparison Study of heparin injection by using intermittent intravenous injection and Continuous Infusion Syringe Pump , on APTT results and possible side effects in patients with acute coronary syndrome (ACS), in 22 Bahman Hospital of Neishabour

Protocol summary

Study aim

Comparison Study of heparin injection by using intermittent intravenous injection and Continuous Infusion Syringe Pump , on APTT results and possible side effects in patients with acute coronary syndrome (ACS), in 22 Bahman Hospital of Nishabour

Design

This research is done as a clinical trial with random allocation with permutation blocks. 2. Research population: All patients have selected based of diagnosis of ACS at 22 Bahman Neishabur Hospital with age of 50 to 75 years old. Patients are divided into two equal groups of 30 people, and in one group, heparin has been injected as an intermittent intravenous every 3 hours at 2500 units, and every 6 hours the sample is sent to control the APTT. If APTT is greater than 100 seconds, one dose will not be injected, but subsequent doses will be repeated in the same way, and the APTT will be controlled repeatedly. In the second group, heparin is injected by using Continuous Infusion Syringe Pump, in the first step, 5000 units are initially injected into a venous block, and then 12 units per kilogram per hour (about 1000 units per hour) are injected by Infusion and APTT is controlled at every 6 hours. If APTT was more than 100 seconds, for one hour infusion interrupted and then it continues again. In both ways, for 48 hours after the start of the test, the APTT test is performed every 6 hours and information is recorded in the patient's APTT examination checklist. Each patient was assigned a code number.

Settings and conduct

This research has been done by considering Ethical considerations and after obtaining permission from the ethics committee of Sabzevar University of Medical Sciences and receiving a letter of introduction to the 22 Bahman Neishabur Hospital and obtaining permission from the hospital authorities and the consent of the patients. The clinical trial have been done on patients with age of 50 to 75 years old with acute coronary syndrome, which includes STEMI-NONSTEMI and unstable angina. . These diagnostics (ACS) are approved by cardiologists. This study was performed after selecting patients with acceptance and not acceptance in CCU1 and CCU2 sections of Neishabour’s 22 Bahman Hospital in 2018. In this study, after the demographic data was recorded the data were recorded as a primary sample other than PTT, PT and INR, the CBC exam is also checked for possible complications (as mentioned in the statement). Patients by using random allocation and permutation blocks, according to the statistical calculation are divided into two equal groups of 30 people, and in one group of patients, heparin is given as an intermittent intravenous injection every 3 hours at 2500 units, and every 6 hours the sample is sent to control the APTT. If APTT is greater than 100 seconds, a dose will not be given, but subsequent doses will be repeated in the same way, and the APTT will be controlled repeatedly. In the second group, infusion pump with syringe pump, 60 units (about 5000 units) are initially injected into a venous block, and then 12 units per kilogram per hour (about 1000 units per hour) are infused continuously and every 6 hours APTT is controlled. If the APTT lasts more than 100 seconds, it will be interrupted for an hour and then will resume again. In both ways, for 48 hours after the start of the test, the APTT test is performed every 6 hours and information is recorded in the patient's APTT examination checklist. (preparation of blood sample for PTT is such that 1.8 cc of the patient's blood in a special tube containing 0.2 cc citrate after placing the lid several times in the palm of your hand, Shake until blood is mixed with citrate inside the tube and then sent to the lab), and in the alternate injection method, heparin is diluted with at least two cc distilled water at a time to

minimize the amount of drug in the angioket route. Both methods are checked four times daily in the APTT. APTT should be 1.5 to 2.5 times the normal range, that is, about 50 to 70 seconds. Then, the obtained results are compared and evaluated according to the criteria of entry and exit. Possible complications associated with heparin (such as hemorrhagic hemorrhage, hematuria, gingival bleeding, blood or vomiting, melena, constipation, cerebral hemorrhage due to reduced consciousness and neurological symptoms, thrombocytopenia, and allergic reactions.

Participants/Inclusion and exclusion criteria

The clinical trial is on patients with age of 50 to 75 years old with acute coronary syndrome, which includes STEMI-NONSTEMI and unstable angina. – inclusion criteria: 1.Acute coronary syndrome upon to the cardiologist's diagnosis. 2.Informed consent for participation in the study. 3. Age in the range of 50 to 70. – Non-acceptance. 4. History of inaccessible bleeding ulcers especially in the gastrointestinal tract, according to the patient's history and previous endoscopy; 5. Active bleeding associated with blood dislocation or tendency to bleed like hemophilia thrombocytopenia; blood cancer; 6 - liver disease leading to coagulation disorders; 7. Presence of suspected intracranial hemorrhage; 8. Presence of thrombophlebitis 9 - presence of wounded or wounded injuries Skin 10. Subacute Endocarditis 11.Existing Renal failure 12 - Excessive Blood Pressure 160 Over 90 Resistant to Treatment 13. Eye or Spinal Cord Operations in Recent Months 14. INR more than 3/5 and the platelets below 100,000 /l 15. Having APTT in excess of 100 Exclusion criteria during research: 1. Dissatisfaction of patient or withdrawal from continuing research or discharging sooner or with personal satisfaction. 2. If the patient experiences complications during the study, such as thrombocytopenia, hemoglobin and hematocrit, gastrointestinal bleeding or allergic reactions. 3. Excessive extent of APTT (more than 2.5 times of normal range) and its consistence after reducing the injected dose. 4. Decrease of Hemoglobin more than 2 mg / dl after injecting heparin.

Intervention groups

The clinical trial on patients with age of 50 to 75 years old with acute coronary syndrome, which includes STEMI-NONSTEMI and unstable angina.

Main outcome variables

1-The activated partial thromboplastin time (APTT) 2.Intermittent intravenous injection of heparin 3-continuous infusion of heparin

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170822035849N4**
Registration date: **2018-04-15, 1397/01/26**
Registration timing: **retrospective**

Last update: **2018-04-15, 1397/01/26**
Update count: **0**

Registration date

2018-04-15, 1397/01/26

Registrant information

Name

Ali Saneipour

Name of organization / entity

Sabzevar University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Sabzevar University of Medical Sciences and personal expenses

Expected recruitment start date

2017-07-23, 1396/05/01

Expected recruitment end date

2017-09-23, 1396/07/01

Actual recruitment start date

2017-09-23, 1396/07/01

Actual recruitment end date

2017-10-07, 1396/07/15

Trial completion date

empty

Scientific title

Comparison Study of heparin injection by using intermittent intravenous injection and Continuous Infusion Syringe Pump , on APTT results and possible side effects in patients with acute coronary syndrome (ACS), in 22 Bahman Hospital of Neishabour

Public title

Comparison of two methods heparin infusion, intermittent intravenous injection and continuous infusion in patients with Acute Coronary Syndrome Disease

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

1. Patients with acute coronary syndrome according to the cardiologist's diagnosis 2- Conscious and informed consent of patients to participate in the study. 3-Being age in the range of 50 to 75 years

Exclusion criteria:

1. History of bleeding ulcers, especially in the gastrointestinal tract 2. The presence of active bleeding accompanied by discoloration of the blood, or a tendency to bleeding like hemophilia, thrombocytopenia, blood cancers 4. Suspicious cases of intracranial bleeding 4.The presence of suspected cases of intracranial hemorrhage 5. Suppurative thrombophlebitis 6. Wounded injuries or the massive loss of skin 7. Subacute endocarditis 8.The presence of renal failure 9. High blood pressure 160 /90 and resistant to treatment 10. Recent eye surgery or spinal cord 11. Higher rang of INR (more

than 3.5)and a platelet below 100,000 12. Having an APTT of more than 100

Age
From **50 years** old to **75 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **60**
More than 1 sample in each individual
Number of samples in each individual: **8**
The sample of this study consist of 60 patients which 30 patients have intermittent injections and 30 other have continuous infusions; and from every person, 8 sample were taken in 48 hours every 6 hours.
Actual sample size reached: **60**
More than 1 sample in each individual
Actual sample size in each individual: **8**
The sample of this study consist of 60 patients which 30 patients have intermittent injections and 30 other have continuous infusions; and from every person, 8 sample were taken in 48 hours every 6 hours.

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, limited randomization was used randomly and the subjects were divided in two equal groups. The first 30 person who were diagnosed with ACS were placed in the continuous infusion group and the next 30 who were admitted to this diagnosis were placed in intermittent intravenous injection.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
The study specification is that in the intermittent intravenous injection method, heparin is injected 30 units per kilogram of body weight, which is injected every three hours.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
The ethics committee of Sabzevar University of Medical Sciences

Street address
BLV,Tohidshahr ,University of Medical Sciences , Sabzevar

City
Sabzevar

Province
Razavi Khorasan

Postal code
9613873136

Approval date
2017-07-18, 1396/04/27

Ethics committee reference number
IR.MEDSAB.REC.1396.35

Health conditions studied

1

Description of health condition studied
Acute coronary syndrome

ICD-10 code
I24

ICD-10 code description
acute ischemic heart diseases

Primary outcomes

1

Description
Activated Partial Thromboplastin Time

Timepoint
By starting heparin injection, sampling has done at every 6 hours, which in 48 hours we have 8 samples for each of patients

Method of measurement
The first, blood sample is taken from the patient, and then poured into an APTT tube and transferred to the lab for testing.

Secondary outcomes

1

Description
Platelets

Timepoint
Before starting heparin in both ways

Method of measurement
Blood platelets measurement

2

Description
The Bleeding

Timepoint
At least every 6 hours as well as if needed

Method of measurement
The measuring instrument are tests, clinical examination and biographies

Intervention groups

1

Description
In this study, the patients were divided into two groups of 30, randomly divided into: 1) intervention group: In the intervention group, the administration of heparin, based on the half-life of it and weight of the patients, was about 2500 units every three hours and APTT controlled for 48 hours every 6 hours.
Category
Treatment - Drugs

2

Description
Control group: Control group: In the control group, heparin was routinely infused with a syringe pump based on body weight with dose of 60 units per kg, per hour and APTT was controlled for 48 hours every 6 hours.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
The 22 Bahman Hospital of Neyshabour
Full name of responsible person
Ali saneipour
Street address
Imam Street., 22 Bahman Hospital of Neyshabour
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
Dr. Fereshteh Gharat
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Sabzevar 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
Sabzevar University of Medical Sciences
Full name of responsible person
Ali Saneipour
Position
Student (Critical Care Nursing)
Latest degree
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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