Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of different dosages of Methylprednisolone on platelet function and fibrinolysis system in cardiopulmonary bypass patients

Protocol summary

Summary

Nowadays cardiopulmonary bypass (CPB) surgery have become very common. During pump time, coagulation and fibrinolysis and also inflammation systems are activated inside the patients body and could result in organ dysfunction. Methylprednisolone is already used to reduce inflammation during CPB. In this study, we are going to assess the effect of two doses of Methylprednisolone (5, 15mg/kg) which is administered during anesthesia on blood losses and blood product requirements; coagulation; fibrinolysis; and the expression of platelet receptors at pre-operation and after heparin neutralization with protamine. 28 patients will be randomly divided into two groups according to the dose of Methylprednisolone (5 or 15mg/kg). Platelet response to different agonists, the expression of platelet receptors (CD41a, CD42b, CD62P), tissue plasminogen activator, plasminogen activator inhibitor, D-dimer will be evaluated pre-operation and after protamine administration. Inclusion criteria are: 1- Patients with coronary artery disease undergoing elective surgery 2- Both male and female patients are eligible 3- between 50 and 70 years old 4- Not having a aspirin 5 days prior to surgery 5- Not using heparin and any other steroid. The blood loss and blood product requirements during operation and ICU room will be measured and compared in the two groups

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201010233438N2**
Registration date: **2010-12-03, 1389/09/12**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2010-12-03, 1389/09/12

Registrant information

Name

Mahnoosh Foroughi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2236 0635

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Recruitment status

Recruitment complete

Funding source

Iran Blood Transfusion Organization(IBTO), Clinical research of Modarres Hospital

Expected recruitment start date

2010-10-23, 1389/08/01

Expected recruitment end date

2010-12-22, 1389/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of different dosages of Methylprednisolone on platelet function and fibrinolysis system in cardiopulmonary bypass patients

Public title

The effect of different dosages of Methylprednisolone on platelet function and fibrinolysis system in cardiopulmonary bypass patients

Purpose

Other

Inclusion/Exclusion criteria
1- Patients with coronary artery disease undergoing elective surgery 2- Both male and female patients are eligible 3- between 50 and 70 years old 4- Not having a aspirin 5 days prior to surgery 5- Not using heparin and any other steroid
Age
From **50 years** old to **70 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **28**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Beheshti Medical University
Street address
Beheshti University, Velenjak, Tehran , Iran
City
Tehran
Postal code
Approval date
2009-10-25, 1388/08/03
Ethics committee reference number
88- 01- 120- 6176- 1345

Health conditions studied

1

Description of health condition studied
Ischeamic heart diseases
ICD-10 code
I25.1
ICD-10 code description
Atherosclerotic heart disease

2

Description of health condition studied
Coagulation defects
ICD-10 code
D68.9
ICD-10 code description
Coagulation defects, unspecified

Primary outcomes

1

Description
Blood loss
Timepoint
24 hour after operation
Method of measurement
Scaled buttel tube

2

Description
Blood product requirements
Timepoint
At operation and ICU room
Method of measurement
The number of bags

Secondary outcomes

1

Description
D-dimer
Timepoint
Pre-operation, after heparin neutralization
Method of measurement
Instrument

2

Description
CK - MB enzyme
Timepoint
Pre-operation, 6, 12 hours after operation
Method of measurement
Instrument

3

Description
Platelet count
Timepoint
Pre-operation, 6, 12 hours after operation
Method of measurement
Instrument

4

Description
HCT
Timepoint

Pre-operation, 6, 12 hours after operation
Method of measurement
Instrument

5

Description
Prothrombin Time
Timepoint
Pre-operation, 6, 12 hours after operation
Method of measurement
Instrument

6

Description
Partial Thromboplastin Time
Timepoint
Pre-operation, 6, 12 houra after operation
Method of measurement
Instrument

7

Description
The expression of platelet receptors
Timepoint
Pre-operation, after heparin neutralization
Method of measurement
Flowcytometry

8

Description
tissue Plasminogen Activator
Timepoint
Pre-operation, after heparin neutralization
Method of measurement
ELISA

9

Description
Platelet response to agonists
Timepoint
Pre-operation, after heparin neutralization
Method of measurement
Aggregometry

10

Description
Plasminogen Activator Inhibitor
Timepoint
Pre-operation, after heparin neutralization
Method of measurement
ELISA

Intervention groups

1

Description
Drug intervention: Methylprednisolone Interavenous, one time, before anesthesia, dose 5mg/kg
Category
Treatment - Drugs

2

Description
Drug intervention: Methylprednisolone Interavenous, one time, before anesthesia, 15mg/kg
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Cardiac center of Modarres Hospital
Full name of responsible person
Dr. Mahnoosh Foroughi
Street address
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran Blood Transfusion Organization(IBTO)
Full name of responsible person
Dr. Maryam Kheirandish
Street address
Iran Blood Transfusion Organization(IBTO), beside of Milad tower, Hemmat freeway, Tehran
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran Blood Transfusion Organization(IBTO)
Proportion provided by this source
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

2

Sponsor
Name of organization / entity

Clinical research of Modarres Hospital
Full name of responsible person
Dr. Mahnoosh Foroughi
Street address
Modarres Hospital, Kaj square, Saadat abad, Tehran
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Clinical research of Modarres Hospital
Proportion provided by this source
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
Clinical research of Modarres Hospital
Full name of responsible person
Dr. Mahnoosh Foroughi
Position
Professor assistant
Other areas of specialty/work
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Person responsible for updating data

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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