

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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

Email address

m_foroughi@sbm.ac.ir

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 hours 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

Street address

Modarres Hospital, Kaj square, Saadat abad, Ttehran

City

Tehran

Postal code

Phone

+98 917 161 3954

Fax

Email

m_foroughi@sbmu.ac.ir

Web page address

Person responsible for scientific 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

Street address

Modarres Hospital, Kaj square, Saadat abad, Tehran

City

Tehran

Postal code

Phone

+98 917 161 3954

Fax

Email

m_foroughi@sbmu.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Clinical research of Modarres Hospital

Full name of responsible person

Dr. Mahnoosh Foroughi

Position

Other areas of specialty/work

Street address

City

Postal code

Phone

Fax

Email

m_foroughi@sbmu.ac.ir

Web page address

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