Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Assessing serum fibrinogen and fibrin degradation products (FDP) changes in hypothermia and normothermia in patients undergoing cardiopulmonary bypass

Protocol summary

Study aim
Determine the frequency of bleeding cases by the presence or absence of coagulation disorders in two groups Determine the relationship between serum levels of fibrinogen and FDP in two groups Determine the relationship between changes in serum fibrinogen and FDP with the duration of hypothermia and normothermia Determination of the relationship between serum fibrinogen and FDP in cardiopulmonary bypass time in two groups Determination of Relationship between Serum Fibrinogen and FDP Levels with Need for Transfusion of Blood and Blood Products in ICU in Two Groups Determination of relationship between serum Fibrinogen and FDP levels with 24-hour bleeding in two groups

Design
Clinical trial, community-based, and pragmatic control group, with parallel, one-blind, randomized,

Settings and conduct
Central Hospital of Shiraz In both groups at 2 times, 2 cc of arterial blood samples were taken and placed in tubes containing tri sodium citrate. The first sample in both groups before the injection of heparin and the onset of CPB and the second sample in the hypothermic group before the onset of rewarming and in the normothermia group with the opening of the cross clamp

Participants/Inclusion and exclusion criteria
Entry requirements: Adult patients undergoing cardiac surgery No entry: All patients with history of thrombosis, bleeding, regular aspirin use in the past 5 days, congenital fibrinogen disorders, liver disease, disorders, or deficiency Coagulation factors, genetic disorders such as hemophilia, chronic renal failure patients, and people with substance abuse

Intervention groups
In the hypothermic group, the degree of water turned the heater-cooler and blanket on 30 ° C and in the noromothermia group at 35 ° C

Main outcome variables
Fibrinogen Fibrinogen degradation products Hypothermia Normothermia

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180930041189N1**
Registration date: **2019-02-10, 1397/11/21**
Registration timing: **retrospective**

Last update: **2019-02-10, 1397/11/21**
Update count: **0**

Registration date
2019-02-10, 1397/11/21

Registrant information

Name
Motahare Ghodrati

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 23 3345 1933

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m.ghodrati87@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-05-22, 1397/03/01

Expected recruitment end date
2018-07-06, 1397/04/15

Actual recruitment start date

2018-07-30, 1397/05/08

Actual recruitment end date

2018-09-06, 1397/06/15

Trial completion date

2018-11-21, 1397/08/30

Scientific title

Assessing serum fibrinogen and fibrin degradation products (FDP) changes in hypothermia and normothermia in patients undergoing cardiopulmonary bypass

Public title

Serum fibrinogen and fibrin degradation products (FDP) changes in hypothermia and normothermia in patients undergoing bypass

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All adult patients undergoing heart surgery Patients between 25 and 85 years

Exclusion criteria:

History of thrombosis bleeding regular aspirin use in the past 5 days congenital fibrinogen disorders liver disease disorders or coagulation deficiencies genetic disorders such as hemophilia chronic renal failure patients people with substance abuse

Age

From **25 years** old to **85 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **80**

Actual sample size reached: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Permutated blocks randomization size 4

Blinding (investigator's opinion)

Single blinded

Blinding description

Participants: After obtaining informed consent, they did not have information on which of the groups they were studying. Clinical caregivers: Clinical caregivers in the ICU did not have a patient group. Examiner Evaluation: The laboratory staff did not know which sample was for which group. Data analyzer: Descriptive data was coded and only researcher was aware of it.

Placebo

Not used

Assignment

Parallel

Other design features

Comparison of fibrinogen in two groups of hypothermia and normothermia and, in particular, fibrinogen degradation products in these two conditions in patients under the bypass

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

Zend Street, opposite the Palestine-Central Building

City

shiraz

Province

Fars

Postal code

71348-14336

Approval date

2018-07-29, 1397/05/07

Ethics committee reference number

IR.SUMS.REC.1397.364

Health conditions studied

1

Description of health condition studied

coronary heart disease

ICD-10 code

I25.1

ICD-10 code description

Atherosclerotic heart disease of native coronary artery

Primary outcomes

1

Description

The amount of fibrinogen consumed and the production of fibrinogen degradation products

Timepoint

At the beginning of the study (before the intervention) and during the bypass in two intervals after the intervention

Method of measurement

Fibrinogen using the clauss and FDP method with serology (kit ELISA)

Secondary outcomes

1

Description

Postoperative bleeding

Timepoint

24 hours after entering ICU

Method of measurement

Measuring Chest tube bleeding

Intervention groups

1

Description

Intervention group: hyporthermic group: In this group, the temperature of the body was reduced untile 30- 34.9 ° C by a heater-cooler and a blanket (temperature changer).

Category

Treatment - Surgery

2

Description

Control group: normothermic group: Coronary artery disease is usually performed at 35- 36.5 ° C.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Central Hospital of Shiraz

Full name of responsible person

Bahram Ghasemzadeh

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Central Building, opposite the Palestine, Zend Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

1396-01-01-15084

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

Yes

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Bahram Ghasemzadeh

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Cardiology

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Initial measurements
When the data will become available and for how long
With the publication of the paper for a month
To whom data/document is available
Persons Investigating in Cardiac Surgery field
Under which criteria data/document could be used
Use the data by naming the people of this study
From where data/document is obtainable
To request data, contact m.ghodrati@gmail.com or call 09355975983.
What processes are involved for a request to access data/document
After receiving the email and accepting the above conditions to identify the researchers, the data will be delivered to the applicant within one day.
Comments