Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Determining the preventive effect of venous fibrinogen on the amount of bleeding during hip arthroplasty surgery

Protocol summary

Study aim
Determining the effect of intravenous fibrinogen administration on reducing bleeding during pelvic joint replacement.

Design
Clinical trial with control group, with parallel groups, double-blind, randomized with dice tose, phase 2 on 110 patients

Settings and conduct
After obtaining informed consent from patients over 18 years of age who are candidates for primary pelvic joint replacement surgery in the operating room of Imam Hossein Hospital in Tehran, patients with uncontrolled underlying disease, previous surgical history in the current operation field, substance abuse, and recent history of coagulation disease or use of anticoagulants prior to hospitalization will be excluded from the study. In the fibrinogen group, patients receive 1 gram of this drug in 50 ml of distilled water through an infusion pump over ten minutes. In the control group, 50 ml of distilled water will be used in the same way as above. An anesthesia technician selects one of the syringes containing fibrinogen or placebo for the patient without informing the anesthesiologist and the patient. The questionnaire is delivered to the first technician.

Participants/Inclusion and exclusion criteria
Patients over 18 years of age who are candidates for primary hip replacement surgery in the operating room of Imam Hossein Hospital in Tehran will be examined after obtaining informed consent. Current operating range, substance use, and recent history of coagulation disease or use of anticoagulants prior to hospitalization will be excluded.

Intervention groups
In the fibrinogen group (case), patients will receive one gram of this drug in a volume of 50 ml of distilled water through an infusion pump within ten minutes of intravenous injection. In the control group, 50 ml of distilled water will be used in the same way as above.

Main outcome variables
Bleeding during surgery Postoperative bleeding

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120910010800N3**
Registration date: **2022-04-05, 1401/01/16**
Registration timing: **prospective**

Last update: **2022-04-05, 1401/01/16**
Update count: **0**

Registration date
2022-04-05, 1401/01/16

Registrant information

Name
Dariush Abtahi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-05-22, 1401/03/01

Expected recruitment end date
2022-09-23, 1401/07/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Determining the preventive effect of venous fibrinogen on the amount of bleeding during hip arthroplasty surgery

Public title
Determining the preventive effect of venous fibrinogen on the amount of bleeding during hip arthroplasty surgery

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
over than 18 years old Consent to the study
Exclusion criteria:
Drug abuse Existence of uncontrolled underlying disease History of any previous surgery within the field of the current operation Recent history of coagulation disease Taking drugs that affect blood clotting before hospitalization

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **110**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients are grouped among the people referring to the operating room of Imam Hossein Hospital (AS) for hip arthroplasty surgery by simple randomization method using coin toss. In such a way that the selection of the case is done in case of tap and the selection of control is done in case of line.

Blinding (investigator's opinion)
Double blinded

Blinding description
Before anesthesia, the other anesthesia technician selects one of the syringes containing fibrinogen (case group) or placebo (control group) for the patient without the knowledge of the anesthesiologist and the patient. After general anesthesia, the infusion is started for all patients. After the surgery, the questionnaire is delivered to the first technician.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of Vice-Chancellor in Research Affairs - Shahid Beheshti University
Street address
Emam Hossein Hospital, Shahid Madani St.
City
Tehran
Province
Tehran
Postal code
1617763141

Approval date
2022-03-13, 1400/12/22

Ethics committee reference number
IR.SBMU.RETECH.REC.1400.1221

Health conditions studied

1

Description of health condition studied
Total hip arthroplasty

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Bleeding during surgery

Timepoint
End of surgery

Method of measurement
The amount of bleeding during the operation will be measured by gas count and suction measurement, as well as the estimation of bleeding at the operation site by an anesthesiologist.

Secondary outcomes

1

Description
Number of units of injected blood products

Timepoint
Up to 24 hours after surgery

Method of measurement
Registration of blood products injection sheet

Intervention groups

1

Description
Intervention group: After induction of anesthesia, one vial of fibrinogen powder equivalent to one gram of it under the brand name HAEMOCOMPLETTAN P Injection, Powder 1 g made by CSL BEHRING company in Germany with 50 ml of distilled water to minimize foam production in the vial It is diluted. The entire amount is drawn into a 50 ml syringe and then injected intravenously using an infusion pump over ten-minutes in a single dose.

Category
Treatment - Drugs

2

Description
Control group: After induction of anesthesia, 50 ml of distilled water is drawn in a 50 ml syringe and then injected intravenously using an infusion pump for ten minutes as a single dose.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Hospital Emam Hossein

Full name of responsible person
Dariush Abtahi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Afshhin Zarghi

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Velenjak، 7th Floor, Bldg No.2 SBUMS, Arabi Ave

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Web page address
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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
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Dariush Abtahi

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

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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
No - There is not 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
Title and more details about the data/document
All data is potentially shareable after unidentified individuals.
When the data will become available and for how long
One year after the publication of the article.
To whom data/document is available
All jobs
Under which criteria data/document could be used
All non-personal patient information (anonymously) can be accessed by contacting the responsible author.
From where data/document is obtainable
email to: drdariushabtahi@yahoo.com
What processes are involved for a request to access data/document
Sending email and review by the responsible author.
Comments