

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jun 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

Country

Iran (Islamic Republic of)

Phone

+98 21 2263 2611

Email address

d.abtahi@sbm.ac.ir

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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<https://www.ehmc.ir>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshhin Zarghi

Street address

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

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Email

Intl_office@sbmu.ac.ir

Web page address

<https://en.sbmu.ac.ir>

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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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Dariush Abtahi

Position

Assistant Professor

Latest degree

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Other areas of specialty/work

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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**Person responsible for updating data****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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