Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jul 2026

The effect of prophylactic administration of intravenous fibrinogen to reduce bleeding during cesarean section

Protocol summary

Study aim
Determining the effectiveness of prophylactic administration of fibrinogen in reducing bleeding during cesarean section

Design
Clinical trial with control group, with parallel groups, double-blind, randomized with dice tose, phase 2 on 105 patients.

Settings and conduct
After obtaining informed consent, all candidates for elective cesarean section 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
All candidates for an elective cesarean section are examined in the operating room at Imam Hossein Hospital in Tehran after obtaining their informed consent. Individuals with uncontrolled underlying disease, a history of prior surgery in the current surgical area, drug use, and a 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: **IRCT20120910010800N8**
Registration date: **2022-11-11, 1401/08/20**
Registration timing: **prospective**

Last update: **2022-11-11, 1401/08/20**
Update count: **0**

Registration date
2022-11-11, 1401/08/20

Registrant information

Name
Dariush Abtahi

Name of organization / entity

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Iran (Islamic Republic of)

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+98 21 2263 2611

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-12-11, 1401/09/20

Expected recruitment end date
2023-03-11, 1401/12/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
The effect of prophylactic administration of intravenous fibrinogen to reduce bleeding during cesarean section

Public title
The effect of administration of fibrinogen in decreasing bleeding in cesarean section.

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Consent to the study

Exclusion criteria:
Drug abuse Existence of uncontrolled underlying disease Recent history of coagulation disease Taking drugs that affect blood clotting before hospitalization

Age
From **18 years** old

Gender
Female

Phase
4

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **105**

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 performing spinal anesthesia, another 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 spinal 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 of Me

Street address
Emam Hossein Hospital, Shahid Madani St.

City
Tehran

Province
Tehran

Postal code
1617763141

Approval date
2022-11-01, 1401/08/10

Ethics committee reference number
IR.SBMU.MSP.REC.1401.378

Health conditions studied

1

Description of health condition studied
Postpartum hemorrhage

ICD-10 code
O72

ICD-10 code description
Postpartum hemorrhage

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
24 hours after surgery

Method of measurement
Registration of blood products injection sheet

Intervention groups

1

Description
Intervention group: After performing spinal 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 performing spinal 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.طبقه بندیplacebo

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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Shahid Madani St

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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

Street address
Tehran Province, Tehran, Velenjak، 7th Floor, Bldg No.2 SBUMS, Arabi Ave

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Intl_office@sbmu.ac.ir

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
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
Not applicable
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