

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

The Effect of Prophylactic Fibrinogen Infusion on intraoperative bleeding during Pelvic Surgery

Protocol summary

Study aim

The effect of fibrinogen prophylactic injection on bleeding during pelvic surgery

Design

A randomized controlled clinical trial with parallel, double-blind, randomized groups

Settings and conduct

Forty-four patients were randomly divided into 21 groups of fibrinogen and placebo. Hemoglobin, platelet and fibrinogen levels are measured in all patients before surgery. In the intervention group after induction, one gram of fibrinogen is injected and the control group is injected with a similar amount in ml of normal saline.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients candidate for non-emergency pelvic surgery undergoing general anesthesia.

Intervention groups

In the intervention group after induction, one gram of fibrinogen is injected and the control group is injected with a similar amount in ml of normal saline.

Main outcome variables

Plasma fibrinogen

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200109046064N1**

Registration date: **2020-02-11, 1398/11/22**

Registration timing: **prospective**

Last update: **2020-02-11, 1398/11/22**

Update count: **0**

Registration date

2020-02-11, 1398/11/22

Registrant information

Name

Majid Charosaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4407 6824

Email address

drch128@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-20, 1398/12/01

Expected recruitment end date

2020-04-20, 1399/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Prophylactic Fibrinogen Infusion on intraoperative bleeding during Pelvic Surgery

Public title

Effect of fibrinogen on bleeding during pelvic surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients candidate for non-emergency pelvic surgery undergoing general anesthesia Satisfaction with study participation Age between 18-60 BMI<30 The preoperative fibrinogen level should be 2-4 g/lit

Exclusion criteria:

cardiovascular, liver, kidney, coagulation and hypertension disorders, diabetes and tumors in surgical

areas. History of use the Beta-Blocker, Calcium Blocker, Digoxin, Tricyclic Antidepressants, Anti-Coagulant and Clonidine A history of alcohol, drug and drug abuse

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **42**

Randomization (investigator's opinion)

Randomized

Randomization description

Using the random number table and quadruple blocks, the following states are obtained and individuals in group A receive fibrinogen and those in group B receive placebo. The above cases include ABAB, AABB, BAAB, BABA, BBAA, ABBA, which are put together by four blocks of states that are completely random and are randomly divided into patients.

Blinding (investigator's opinion)

Double blinded

Blinding description

To blind and hide the specimens, a special code was written for each patient in a sealed envelope that only by a researcher opened the envelope just prior to attempting to anesthetize the patient in complete confidentiality

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, Next to Milad Tower, Hemmat Highway

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2018-04-29, 1397/02/09

Ethics committee reference number

IR.IUMS.FMD.REC.1396.9511174006

Health conditions studied

1

Description of health condition studied

Pelvic Surgery

ICD-10 code

S32.7

ICD-10 code description

Multiple fractures of lumbar spine and pelvis

Primary outcomes

1

Description

Plasma fibrinogen

Timepoint

Before and after surgery

Method of measurement

Based on the patient's blood laboratory results

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Before surgery, one gram of prophylactic fibrinogen infusion (made by the Marburg factory in Germany) is performed in 50 ml of normal saline within five minutes after induction of anesthesia.

Category

Treatment - Drugs

2

Description

Control group: Before surgery, normal saline infusion is performed.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Firoozgar Hospital

Full name of responsible person

Majid Charousaie

Street address

Firoozgar Hospital, Afarin Ave, Karim Khan Street, Valiasr Square

City
Tehran
Province
Tehran
Postal code
۱۵۹۳۷۴۷۸۱۱
Phone
+98 21 8214 1600
Email
drch128@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Seyed Abbas Motevalian
Street address
Iran University of Medical Sciences, Next to Milad
Tower, Hemmat Highway
City
Tehran
Province
Tehran
Postal code
۱۴۴۹۶۱۴۵۳۵
Phone
+98 21 8670 2504
Email
research-m@iums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iran 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
Iran University of Medical Sciences
Full name of responsible person
Majid Charousaie
Position
Resident
Latest degree

Medical doctor
Other areas of specialty/work
Anesthesiology
Street address
Firoozgar Hospital, Afarin Ave, Karim Khan Street,
Valiasr Square
City
Tehran
Province
Tehran
Postal code
۱۵۹۳۷۴۷۸۱۱
Phone
+98 21 8214 1600
Email
drch128@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Majid Charousaie
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Anesthesiology
Street address
Firoozgar Hospital, Afarin Ave, Karim Khan Street,
Valiasr Square
City
Tehran
Province
Tehran
Postal code
۱۵۹۳۷۴۷۸۱۱
Phone
009882141600
Email
drch128@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Majid Charousaie
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Anesthesiology
Street address
Firoozgar Hospital, Afarin Ave, Karim Khan Street,
Valiasr Square
City

Tehran
Province
Tehran
Postal code
۱۵۹۳۷۴۷۸۱۱
Phone
+98 21 8214 1600
Email
drch128@gmail.com
Web page address

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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

All potential data is shared after unidentifiable people.

When the data will become available and for how long

Start of access period 6 months after printing results

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

There are no special conditions.

From where data/document is obtainable

Majid Charousaie

What processes are involved for a request to access data/document

After reviewing the applicant's request, it will be sent to him.

Comments