

# 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**  
Rezident  
**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**  
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**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**  
Rezident  
**Latest degree**  
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**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**  
Rezident  
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+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**