

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jun 2026

Effect of Local Fibrinogen Administration on postoperative bleeding in open Prostatectomy surgery

Protocol summary

Study aim

Effect of Local Fibrinogen Administration on postoperative bleeding in open Prostatectomy surgery

Design

In this research, 44 eligible patients candidate for open Prostatectomy surgery were chosen and a code was allocated to each one of them. Then, patients were randomly divided into two control and intervention groups.

Settings and conduct

This study will be conducted in the Emam khomeini hospital general operating room. The Patients and surgeon will not be aware of the drug used and the division of the groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria are the Patients candidate for elective open prostatectomy surgery, Preoperative serum fibrinogen level between 2-4 g/l, ASA I,II , Age 45-70 years old. Exclusion criteria are the emergent or urgent surgery; Age more than 70 years or less than 45 years old; History of deep vein thrombosis; History of underlying hematologic disorders

Intervention groups

Drug: Fibrinogen: - Dose: 500 Milligram - Number of using: Once - Factory name: B Braun - Manufacturing Country's Name: Germany - Location prescribed: Local - Administration time: End of Surgery. Placebo: Normal Saline: - Dose: 10 milliliter - Number of using: Once - Factory name: Abureihan Corporation - Manufacturing Country's Name: Iran - Location prescribed: Local - Administration time: End of Surgery

Main outcome variables

Bleeding during and after prostatectomy and the use of blood products will be recorded up to 24 hours after the operation.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170421033564N1**

Registration date: **2018-01-21, 1396/11/01**

Registration timing: **prospective**

Last update: **2018-01-21, 1396/11/01**

Update count: **0**

Registration date

2018-01-21, 1396/11/01

Registrant information

Name

Mohammed Reza Ghandizadeh Dezfuli

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3377 5494

Email address

ghandizadehdezfuli.m@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-03, 1397/01/14

Expected recruitment end date

2018-08-05, 1397/05/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Local Fibrinogen Administration on postoperative bleeding in open Prostatectomy surgery

Public title

Effect of Local Fibrinogen Administration on postoperative bleeding in open Prostatectomy surgery

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Inclusion criteria: Patients candidate for elective open prostatectomy surgery, Preoperative serum fibrinogen level between 2-4 g/l, ASA I,II , Age 45-70y

Exclusion criteria:

Exclusion criteria: Emergent or urgent surgery; Age more than 70 years or less than 45 years old; History of deep vein thrombosis; History of underlying hematologic disorders

Age

From **45 years** old to **70 years** old

Gender

Male

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description

Patients will not have information about the categories of groups. The drug or placebo was prepared by a person who did not intervene in the surgery process and postoperative care.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethic Committee of Ahvaz Jundishapur University of Medical Sciences

Street address

No 3, University street, Golestan Blvd, Ahvaz

City

Ahvaz

Province

Khouzestan

Postal code

6135785689

Approval date

2017-03-11, 1395/12/21

Ethics committee reference number

816.1395.rec.ajums.ir

Health conditions studied**1****Description of health condition studied**

Benign Prostate Hypertrophy

ICD-10 code

N40

ICD-10 code description

Enlarged Prostate

Primary outcomes**1****Description**

Bleeding during and after Prostatectomy surgery

Timepoint

End of surgery and 24 hours after surgery

Method of measurement

Observe

Secondary outcomes**1****Description**

Volume of administered blood product

Timepoint

Twenty four hours after surgery

Method of measurement

Milliliter

Intervention groups**1****Description**

Intervention group: Drug : Fibrinogen Dose: 500 mg
Number of using: Once Factory name: CSL Behring
Company Manufacturing Country's Name: USA Location
prescribed: Local Administration time: End of Surgery

Category

Prevention

2**Description**

Control group: Placebo: Normal Saline: Dose: 10
Milliliter Number of using: Once Factory name: Abureihan
Company Manufacturing Country's Name: Iran Location
prescribed: Local Administration time End of surgery

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Educational Hospital

Full name of responsible person

Dr Nozar Nasajian

Street address

No. 307, Kokab Street, Masters Alley, Golestan Blvd.

City

Ahvaz

Province

Khouzestan

Postal code

6715734346

Phone

+98 61 1356 8976

Email

nozar-dr@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Dr. Mostafa Feghhi

Street address

No. 21, Ave. 1, Golestan Blvd.

City

Ahvaz

Province

Khouzestan

Postal code

6135764789

Phone

+98 61 1356 8759

Email

mostafafatahi777@gmail.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Mohamad Reza Ghandizadeh Dezfuli

Position

Resident

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

No. 12, Enghelab Chamber, Golestan Blvd.

City

Ahvaz

Province

Khouzestan

Postal code

6134578569

Phone

+98 61 1356 9857

Email

ghandizadehdezfuli.m@ajums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mohamad Reza Ghandizadeh Dezfuli

Position

Resident

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

No. 12, Enghelab Chamber, Golestan Blvd.

City

Ahvaz

Province

Khouzestan

Postal code

6135896478

Phone

+98 61 3377 5494

Email

ghandizadehdezfuli.m@ajums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mohamad Reza Ghandizadeh Dezfuli

Position

Resident

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

No. 12, Enghelab Chamber, Golestan blvd

City

Ahvaz

Province

Khouzestan

Postal code

6135786985

Phone

+98 61 3222 8532

Fax

+98 61 3222 8533

Email

mostafafatahi777@gmail.com

Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Patient privacy

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be 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