

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

The Effect of Fibrinogen Injection on Bleeding in Total Knee Arthroplasty

Protocol summary

Study aim

Determine the effect of fibrinogen Injection on the

Design

Patients are randomly divided into intervention and control groups and the study is design as a randomised, controlled, parallel group trial with double blinded outcome assessment. Randomisation was centralised based on randomized block randomization method.

Settings and conduct

Fifty eight patients candidate of Total Knee Arthroplasty with age group 40-70 years are randomly divided by quadruple random permutations method into intervention (intra-articular infusion of 500 mg of fibrinogen dissolved powder in 10 ml normal saline) and control (intra-articular infusion of 10 ml normal saline) group. Patient, surgeon and researcher do not have any information on how to place people in groups. Post-operative bleeding, hemoglobin, prothrombin time, partial thromboplastin time, hematocrit and plasma level of fibrinogen are measured in 0, 6 and 24 hours after surgery in two groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria are patients candidate of Total Knee Arthroplasty (TKA), Age group 40-70 years, American Society of Anesthesiologists (ASA) classification I, II; The exclusion criteria are patients with cardiovascular diseases, patients with anemia or bleeding disorders, history of knee arthroscopy, consumption of Anticoagulant medications, history of knee arthroscopy, history of deep vein thrombosis and high body mass index.

Intervention groups

In the Intervention group, local injection of 500 mg of fibrinogen dissolved powder manufactured by CSL USA in 10 ml normal saline and in the control group local injection of 10 ml normal saline is done in the knee joint 2 minutes before opening tourniquet.

Main outcome variables

Bleeding after surgery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190222042803N1**

Registration date: **2019-03-10, 1397/12/19**

Registration timing: **registered_while_recruiting**

Last update: **2019-03-10, 1397/12/19**

Update count: **0**

Registration date

2019-03-10, 1397/12/19

Registrant information

Name

Hojatollah Khadem Ali

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 61 3337 4303

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-20, 1397/12/01

Expected recruitment end date

2019-07-23, 1398/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Fibrinogen Injection on Bleeding in Total

Knee Arthroplasty

Public title

The Effect of Fibrinogen Injection on Bleeding in Total Knee Arthroplasty

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Patients candidate of Total Knee Arthroplasty (TKA) Age group 40-70 years American Society of Anesthesiologists (ASA) classification I , II

Exclusion criteria:

Patients with cardiovascular diseases Patients with anemia or bleeding disorders Consumption of Anticoagulant medications History of knee arthroscopy History of deep vein thrombosis High Body Mass Index

Age

From **40 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size

Target sample size: **58**

Randomization (investigator's opinion)

Randomized

Randomization description

Individuals are randomly divided into two groups based on randomized block randomization method. Randomized blocks are used for this purpose. A random sample based on this method from Sealedenvelope.com has been extracted.

Blinding (investigator's opinion)

Double blinded

Blinding description

Considering that after dissolving fibrinogen in normal saline, no difference in color compared with normal saline solution, it can be said that the patient, surgeon and data analyzer do not have any information on how to place patients in the groups.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahvaz University of Medical Sciences

Street address

Research deputy, Ahvaz Jundishapur University Of Medical Sciences, Golestan Blvd.

City

Ahvaz

Province

Khouzestan

Postal code

6135715794

Approval date

2018-04-16, 1397/01/27

Ethics committee reference number

IR.AJUMS.REC.1397.419

Health conditions studied

1

Description of health condition studied

Total Knee Arthroplasty

ICD-10 code

M23.4

ICD-10 code description

Loose body in knee

Primary outcomes

1

Description

Post-operative bleeding

Timepoint

0, 6 and 24 hours after surgery

Method of measurement

Blood volume in Hemovac

Secondary outcomes

1

Description

Hemoglobin

Timepoint

0, 6 and 24 hours after surgery

Method of measurement

Blood test

2

Description

Prothrombin time (PT)

Timepoint

0, 6 and 24 hours after surgery

Method of measurement

Blood test

3

Description

Partial thromboplastin time (PTT)

Timepoint

0, 6 and 24 hours after surgery

Method of measurement

Blood test

4**Description**

Hematocrit (HCT)

Timepoint

0, 6 and 24 hours after surgery

Method of measurement

Blood test

5**Description**

Plasma level of fibrinogen

Timepoint

0, 6 and 24 hours after surgery

Method of measurement

Blood test

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

Intervention group: Local injection of 500 mg of fibrinogen dissolved powder manufactured by CSL Behring USA in 10 ml of normal saline in the knee joint 2 minutes before opening tourniquet

Category

Prevention

2**Description**

Control group: Local injection of 10 ml normal saline in the knee joint 2 minutes before opening tourniquet

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Golestan Hospital, Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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Grant name**Grant code / Reference number**

PAIN-9706

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

Hojatollah Khadem Ali

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

Study Protocol

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

Statistical Analysis Plan

Not applicable

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

Not applicable

Data Dictionary

Not applicable