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
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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
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Province
Khouzestan
Postal code
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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
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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
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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