

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

The Effect of Fibrinogen on Bleeding Rates in Lumbar Surgery

Protocol summary

Study aim

To investigate the effects of fibrinogen on bleeding rates in patients undergoing lumbar surgeries

Design

Randomized, controlled, parallel group trial with blinded outcome assessment. Randomization was centralized with simple randomization with random number tables

Settings and conduct

Researchers responsible for data collection and analyses are blind to the groups allocation

Participants/Inclusion and exclusion criteria

Inclusion criteria are patients who are candidate of lumbar surgery, age range 18 to 60 years old; The exclusion criteria are patients with cardiovascular diseases, anemia or bleeding disorders, consumption of anticoagulant medications and history of spinal surgery

Intervention groups

Twenty eight patients are randomly assigned into control and intervention groups (n=14 cases). In the Intervention group, at the beginning of surgical incision, Fibrinogen (1 mg) with 50 cc distilled water is administered. In the control group, at the beginning of surgical incision, 50 cc distilled water is administered.

Main outcome variables

Serum fibrinogen level; PTT; PT; HCT; and HB

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180811040763N1**

Registration date: **2018-09-01, 1397/06/10**

Registration timing: **registered_while_recruiting**

Last update: **2018-09-01, 1397/06/10**

Update count: **0**

Registration date

2018-09-01, 1397/06/10

Registrant information

Name

Mohsen Shafaei Tonekaboni

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3374 3001

Email address

shafaei.m@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-07, 1397/05/16

Expected recruitment end date

2018-11-07, 1397/08/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Fibrinogen on Bleeding Rates in Lumbar Surgery

Public title

Fibrinogen effect on bleeding rates in surgeries

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients candidate of lumbar surgery Age range: 18 to 60 years old

Exclusion criteria:

Patients with cardiovascular diseases Patients with anemia or bleeding disorders Consumption of anticoagulant medications History of spinal surgery

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **28**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization with random number tables

Blinding (investigator's opinion)

Single blinded

Blinding description

Researchers responsible for data collection and analyses are blind to the groups allocation.

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

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

City

Ahvaz

Province

Khuzestan

Postal code

6135715794

Approval date

2017-12-09, 1396/09/18

Ethics committee reference number

IR.AJUMS.REC.1396.1136

Health conditions studied

1

Description of health condition studied

Lumbar discopathy

ICD-10 code

M51.1

ICD-10 code description

Lumbar and other intervertebral disc disorders with radiculopathy

Primary outcomes

1

Description

Serum fibrinogen level

Timepoint

Before anesthesia induction (pre-intervention), immediately, 6 and 24 hours after the completion of the surgical operation

Method of measurement

Blood test

2

Description

Partial Thromboplastin Time (PTT)

Timepoint

Before anesthesia induction (pre-intervention), immediately, 6 and 24 hours after the completion of the surgical operation

Method of measurement

Blood test

3

Description

Prothrombin Time (PT)

Timepoint

Before anesthesia induction (pre-intervention), immediately, 6 and 24 hours after the completion of the surgical operation

Method of measurement

Blood test

4

Description

Hematocrit (HCT)

Timepoint

Before anesthesia induction (pre-intervention), immediately, 6 and 24 hours after the completion of the surgical operation

Method of measurement

Blood test

5

Description

Hemoglobin (HB)

Timepoint

Before anesthesia induction (pre-intervention), immediately, 6 and 24 hours after the completion of the surgical operation

Method of measurement

Blood test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: At the beginning of surgical incision, Fibrinogen (1 mg) with 50 cc distilled water is administered.

Category

Treatment - Drugs

2

Description

Control group: At the beginning of surgical incision, 50 cc distilled water is administered.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Golestan Hospital, Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Fatemeh Javaherforooshzadeh

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Farvardin Ave., Golestan Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mohammad Badavi, PhD

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Deputy of Research, Ahvaz Jundishapur University of Medical Sciences, Golestan Blvd.

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Grant name

Grant code / Reference number

330093556

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

Mohsen Shafaei Tonekaboni

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

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Assistant professor

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Subspecialist

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Person responsible for updating data**Contact****Name of organization / entity**

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Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

Street address

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City

Ahvaz

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

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

Not applicable

Data Dictionary

Not applicable