Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jul 2026

Role of topical tranexamic acid in reducing perioperative blood loss in traumatic and non-traumatic patients undergoing posterior lumbar spinal surgery

Protocol summary

Study aim

To identify the effect of topical tranexamic acid on bleeding during posterior spinal surgery in traumatic and non-traumatic patients

Design

Randomized , double blind two arm parallel group clinical trial , phase 3 on 104 participant . Randlist. software was used for randomization.

Settings and conduct

Traumatic and non-traumatic patients undergoing PLS surgery in Baqiatallah Hospital, Tehran on 1399 will be enrolled. 3 gr TXA in 100 cc saline for case group.

Participants/Inclusion and exclusion criteria

Including criteria: Patients aged 18 to 75 years; Traumatic patients (during the first 3 weeks after injury); Non-traumatic patients (with a maximum of 4 levels of involvement); The need for posterior lumbar surgery Excluding criteria: Requires emergency surgery with non-neurosurgical indications; Bleeding more than 1 liter before surgery in cases of trauma; History of thromboembolism; Treatment with anticoagulants; Treatment with antiplatelets; Treated with other drugs that disturb coagulation such as sodium valproate; Any Transexamic acid intake before (eg polymenorrhea in women or in dentistry); Penetrating spinal trauma; Hemodynamical instability; History of seizures; Liver disfuction; Renal dysfunction; Abnormal results of laboratory coagulation tests; Patient's reluctance;

Intervention groups

Circular nurse will make solution of 3 grams of tranexamic acid in 100 ml of normal saline for the case group, which uses for repeated washing and moistening of sterile gas for packing, and in the control group, only normal saline will use. The standard treatment is normal saline alone.

Main outcome variables

Bleeding volume will be recorded after the operation. The length of postoperative hospitalization will record by day. Coagulation laboratory tests will perform. At the follow-up visit, the patient will asked about the returning to work. Any systemic complication will be recorded.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200203046351N1**
Registration date: **2020-12-16, 1399/09/26**
Registration timing: **registered_while_recruiting**

Last update: **2020-12-16, 1399/09/26**
Update count: **0**

Registration date

2020-12-16, 1399/09/26

Registrant information

Name

Mohammad Eslamian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6659 6934

Email address

md.eslamian@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-04, 1399/09/14

Expected recruitment end date

2021-02-22, 1399/12/04

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Role of topical tranexamic acid in reducing perioperative blood loss in traumatic and non-traumatic patients undergoing posterior lumbar spinal surgery

Public title

topical tranexamic acid in perioperative blood loss of the posterior lumbar spinal surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with age between 18 to 75 years . Patients whom needs posterior lumbar spinal surgery Traumatic patients (in the first 3 weeks after injury) Non-traumatic patients (with maximum 4 spinal level envolved)

Exclusion criteria:

History of thromboembolism Emergent surgery with indications other than neurosurgical indications Treatment with other drugs that affect blood coagulation such as sodium valproate Any transexamic acid intake before (eg polymenorrhea in women or in dentistry) Treatment with anticoagulants Treatment with antiplatelets Spinal penetrating injury Hemodynamical unstability History of epilepsy or seizure Liver malfunction Renal failure Abnormal results of laboratory coagulation tests Patient's reluctance

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **104**

Randomization (investigator's opinion)

Randomized

Randomization description

By usage of Randlist software, each participant will be assigned a random number. Even numbers will enter in the intervention group and odd numbers will be the placebo group. Another person who is unaware of the randomization and has not take part in the intervention, prepares the solution for washing during the operation based on the even or odd code of the patients. The randomization method is simple and the unit is individual randomization.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients, surgeon and the anesthesia team are blinded to intervention. Based on the codes, The same operating room technician will use medication in the case group and in the control group only normal saline is used.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Baqiyatallah Hospital

Street address

No 37, Dr Sahriati Ave

City

Hamedan

Province

Hamadan

Postal code

6516676794

Approval date

2019-12-21, 1398/09/30

Ethics committee reference number

IR.BMSU.BAQ.REC.1398.001

Health conditions studied

1

Description of health condition studied

هرنی دیسک کمر

ICD-10 code

M51.26

ICD-10 code description

Other intervertebral disc displacement, lumbar region

2

Description of health condition studied

شکستگی مهره های کمری ستون فقرات

ICD-10 code

S32.009A

ICD-10 code description

Unspecified fracture of unspecified lumbar vertebra, initial encounter for closed fracture

Primary outcomes

1

Description

Intraoperative blood loss

Timepoint

At the end of the operation

Method of measurement

with use of standard anesthesia chart by ml

Secondary outcomes

1

Description

Duration of hospitalization

Timepoint

Time of discharge

Method of measurement

Questionnaire

2

Description

coagulation studies

Timepoint

At the beginning of the study and post op

Method of measurement

questionnaire

3

Description

Duration of returning to work

Timepoint

2 month post op

Method of measurement

questionnaire

Intervention groups

1

Description

Intervention group: solution of 3 gr TXA in 100 cc normal saline will use for intermittent washing and soaking sterile gases for packing.

Category

Treatment - Drugs

2

Description

Control group: Normal saline

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Baqiatallah Hospital

Full name of responsible person

Eslamian , Mohammad

Street address

Mollasadra ave

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Tehran

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1435916471

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+98 21 8755 5250

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md.eslamian@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Dr.Gholamhosin Alishiri

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R.bmsu@yahoo.com

Web page address

https://research.bmsu.ac.ir/portal/home/

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Bagheiat-allah 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

Tehran University of Medical Sciences

Full name of responsible person

Eslamian, Mohammad

Position

Non-faculty specialist physician

Latest degree
Specialist
Other areas of specialty/work
Neurosurgery
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Person responsible for scientific inquiries

Contact
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Position
Researcher
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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
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
all of the data can be shared.
When the data will become available and for how long
6 months after publication
To whom data/document is available
Researchers of university centers
Under which criteria data/document could be used
Maintain data security Permission of the financing organization and the research center
From where data/document is obtainable
E-mail
What processes are involved for a request to access data/document
After submitting the request, coordination will be done with the research center of the study and the data collection canter and will be sent after approval. The process will take about 2 months.
Comments