Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of systemic Tranexamic acid injection with topical in reduction of bleeding during and after spinal surgery

Protocol summary

Study aim
Comparison of systemic Tranexamic acid injection with topical in reduction of bleeding during and after spinal surgery
Design
The study is a randomized, community-based, and pragmatic clinical trial consisting of 100 patients in 2 parallel groups with a double-blind design
Settings and conduct
This study will be carried out at Tabriz Imam Reza Hospital in a two-blind manner,
Participants/Inclusion and exclusion criteria
Inclusion criteria: 1) patients aged 15 to 75 years 2). Candidates to the spinal fixation surgery Agreed to participator.3) Having informed consent to participate in the study. Exit criteria: 1. History of abnormal bleeding 2. Platelet is less than 150 thousand 3. History of Thrombosis 4. Consumption of interfering drugs with blood Homeostasis 5. Overweight (BMI>30)
Intervention groups
Intervention group1: Systemic tranexamic acid in first before the skin incision 10 mg per kg body weight as the initial bolus dose and then 1 mg per kg body weight every hour until the end of surgery by infusion.Intervention group 2: The same conditions continue as in intervention group 1, but eventually a topical dose of 50 mg per ml as a solution of normal saline will be used for the required serum consumption for rinsing from the beginning to the end of the operation.
Main outcome variables
Bleeding, Length of hospitalization

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20120527009878N14**
Registration date: **2021-12-19, 1400/09/28**
Registration timing: **registered_while_recruiting**

Last update: **2021-12-19, 1400/09/28**
Update count: **0**
Registration date
2021-12-19, 1400/09/28

Registrant information
Name
Firooz Salehpour
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2021-04-21, 1400/02/01
Expected recruitment end date
2022-05-20, 1401/02/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of systemic Tranexamic acid injection with topical in reduction of bleeding during and after spinal surgery

Public title
systemic Tranexamic acid injection with topical in spinal

surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Candidates to the spinal fixation surgery Agreed to participator

Exclusion criteria:

History of abnormal bleeding Platelet less than 150 thousands History of Thrombosis Consumption of interfering drugs with blood Homeostasis Overweight (BMI>30)

Age

From **15 years** old to **75 years** old

Gender

Both

Phase

1-2

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, individuals were assigned to two groups using the permutation block method. In this method, a represents the individual receiving the systemic tranexamic acid and B represents the individual in the topical tranexamic acid group. Considering the quadruple block; they were classified into AABB, ABAB, ABBA, BAAB BBAA, and BABA permutations, and by random selection from permutation patients were classified

Blinding (investigator's opinion)

Double blinded

Blinding description

The treatment assessor and the statistical analyst will not be aware of the allocation of intervention until the end of the study.se group.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tabriz Medical School

Street address

Azadi Ave , Golghast St , Imam Reza Hospital

City

Tabriz

Province

East Azarbaijan

Postal code

5166614756

Approval date

2021-07-12, 1400/04/21

Ethics committee reference number

IR.TBZMED.REC.1400.363

Health conditions studied

1

Description of health condition studied

The effect of Tranexamic Acid for bleeding in Spinal Surgery

ICD-10 code

D69.9

ICD-10 code description

Hemorrhagic condition, unspecified

Primary outcomes

1

Description

Bleeding

Timepoint

During surgery till 48 hours after surgery

Method of measurement

Number of pads and amount of suction blood during surgery

Secondary outcomes

1

Description

Length of hospitalization during laminectomy and in spinal fusion

Timepoint

During surgery and duration of hospitalization after surgery

Method of measurement

Duration of hospitalization in hospital days

2

Description

the amount of blood collected in hemovac in patients undergoing laminectomy and in spinal fusion

Timepoint

Duration of hospitalization after surgery

Method of measurement

The amount of blood accumulated in CC

Intervention groups

1

Description
Intervention group: Systemic tranexamic acid in first before the skin incision 10 mg per kg body weight as the initial bolus dose and then 1 mg per kg body weight every hour until the end of surgery by infusion

Category
Treatment - Surgery

2

Description
Intervention group 2: The same conditions continue as in intervention group 1, but eventually a topical dose of 50 mg per ml as a solution of normal saline will be used for the required serum consumption for rinsing from the beginning to the end of the operation.

Category
Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center
Neurosurgery Ward of Emem Reza hospital

Full name of responsible person
Ali Asghar Asghari

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Ali Meshkini

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Vice chancellor for research, Tabriz University of Medical Sciences, Daneshgah Avenue, Daneshgah Square

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Meshkinia@gmail.com

Grant name

Grant code / Reference number

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

Title of funding source
Tabriz 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
Tabriz University of Medical Sciences

Full name of responsible person
Dr.Farhad Mirzaei

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Neurosurgery

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
No - There is not 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
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
Title and more details about the data/document
A portion of the data that represents the final outcome
When the data will become available and for how long
Access will be 6 months after the results are printed
To whom data/document is available
Neuropsychiatric specialists in coordination with the presenter
Under which criteria data/document could be used
The use of data to improve patients' treatment processes is safe
From where data/document is obtainable
Person responsible for updating study information
What processes are involved for a request to access data/document
Requesting data and study documents will be done by correspondence with the person responsible for updating the study information
Comments