

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 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

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3334 0830

Email address

salehpourf@tbzmed.ac.ir

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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Azadi St. Golghast St.

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ali.tmv@gmail.com

Web page address

<https://imamreza.tbzmed.ac.ir>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Ali Meshkini

Street address

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

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Email

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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Neurosurgery ward, Emam Reza Hospital, Gholghasht Street, Azadi Street

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golzar.farhad@yahoo.com

Person responsible for scientific 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

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

Tabriz University of Medical Sciences

Full name of responsible person

Ali Asghar Asghari

Position

Resident of Neurosurgery

Latest degree

Medical doctor

Other areas of specialty/work

Neurosurgery

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