Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of the effects of topical versus intravenous tranexamic acid on reducing bleeding in patients undergoing head and neck surgeries: A double-blind clinical trial.

Protocol summary

Study aim
The objective of this study is to compare the effect of topical versus intravenous tranexamic acid in reducing the amount of bleeding in patients undergoing head and neck surgeries.

Design
This is a randomized, double-blind, parallel-group clinical trial. Randomization was performed using random number tables, and the sample size is set at 60 patients.

Settings and conduct
The study will be conducted at Imam Reza Hospital, Mashhad. Patients will be randomly assigned to one of the groups, and head and neck surgeries will be performed under specialist supervision. Blinding is applied for both patients and the medical

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients aged 18 to 80 years undergoing head and neck surgeries, such as unilateral head and neck cancer, unilateral neck dissection, mandible resection, thyroidectomy, parotidectomy; Exclusion criteria: Patients with a history of coagulopathy, renal or liver disorders, allergy to tranexamic acid, or recent use of anticoagulant drugs.

Intervention groups
First group: Intravenous administration of tranexamic acid at a dose of 20 mg/kg; second group: topical administration of tranexamic acid at 25 mg/ml; control group: intravenous and topical administration of normal saline.

Main outcome variables
Postoperative bleeding volume; need for blood transfusion; postoperative complications.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20231124060157N1**
Registration date: **2024-10-05, 1403/07/14**
Registration timing: **retrospective**

Last update: **2024-10-05, 1403/07/14**
Update count: **0**

Registration date
2024-10-05, 1403/07/14

Registrant information
Name
samieerad سمیعی راد
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-02-18, 1402/11/29

Expected recruitment end date
2024-05-19, 1403/02/30

Actual recruitment start date
2024-02-18, 1402/11/29

Actual recruitment end date
2024-04-17, 1403/01/29

Trial completion date
2024-04-20, 1403/02/01

Scientific title
Comparison of the effects of topical versus intravenous tranexamic acid on reducing bleeding in patients

undergoing head and neck surgeries: A double-blind clinical trial.

Public title
Evaluation of the effect of topical versus intravenous tranexamic acid on reducing bleeding in head and neck surgeries
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients undergoing head and neck surgeries, including unilateral head and neck cancer surgery, unilateral neck dissection, mandible resection, thyroidectomy, and parotidectomy.
Exclusion criteria:
Patients with a history of uncontrolled bleeding or severe coagulation disorders. Patients with a known allergy to tranexamic acid. Patients with severe renal impairment (creatinine > 1.2). Patients with severe liver disease. Patients with recent use of anticoagulant medications (heparin or warfarin). Patients with a history of prior surgery or radiotherapy in the neck region. Patients with severe peripheral vascular diseases. Patients with a recent history of stroke or cardiovascular diseases.
Age
From **18 years** old to **80 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **40**
Actual sample size reached: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization Method: The study will use block randomization to ensure an equal number of participants in each group. In each block, four participants will be randomly assigned to the different intervention and control groups. Unit of Randomization: The unit of randomization is individual; each patient is individually assigned to one of the groups. Stratified Randomization: There is no use of stratified randomization in this study. Randomization Tool: The randomization sequence will be generated using a table of random numbers provided by the software randomization.com. This tool generates the random sequence for allocating participants to the groups. Generation of Random Sequence: The random sequence will be created using randomization.com, based on blocks of four. The sequence will be stored in sealed envelopes, and for each patient, an envelope will be opened to assign the patient to one of the groups. Allocation Concealment: Allocation concealment will be maintained using sealed opaque envelopes. Each envelope contains a code that indicates which group the patient will be assigned to (intervention or control). These envelopes remain sealed until the patient is enrolled in the study and opened by blinded investigators.
Blinding (investigator's opinion)
Double blinded
Blinding description
A pharmacist is responsible for preparing the drugs and materials used, and all medications are prepared in containers or syringes labeled only with the patient's number. This ensures that neither the treatment team nor the patient knows whether the solution contains tranexamic acid or a placebo. Patients are randomly assigned to one of the groups (intervention or control) without knowing which group they belong to. Postoperative outcomes and complications are assessed by independent evaluators who are blinded to the group allocation of the patients.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Mashhad university of medical sciences
Street address
Danseshgah street
City
Mashhad
Province
Razavi Khorasan
Postal code
9138813944
Approval date
2022-05-31, 1401/03/10
Ethics committee reference number
IR.MUMS.MEDICAL.REC.1401.376

Health conditions studied

1

Description of health condition studied
Postprocedural shock
ICD-10 code
T81.1
ICD-10 code description
Postprocedural shock

2

Description of health condition studied
Neoplasm of uncertain behavior of bone and articular

cartilage

ICD-10 code

D48.0

ICD-10 code description

Neoplasm of uncertain behavior of bone and articular cartilage

3

Description of health condition studied

Malignant neoplasm of head, face and neck

ICD-10 code

C76.0

ICD-10 code description

Malignant neoplasm of head, face and neck

Primary outcomes

1

Description

Post-operating bleeding

Timepoint

The amount of postoperative bleeding is measured at the following time points:Before the surgery (to establish baseline hemoglobin and platelet levels).During the first 24 hours after surgery (blood collection from the drain).Every subsequent 24 hours until the drain is removed (typically when the output is less than 20 milliliters per day for two consecutive days)

Method of measurement

Postoperative bleeding is measured using the gravimetry technique (weighing the blood drained from surgical drains). In addition, the volume of blood collected in the suction bag is measured. Hemoglobin and platelet levels are recorded before and after surgery using a complete blood count (CBC) test.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group (A): Recipients of 20 mg/kg intravenous tranexamic acid in 100 cc normal saline.

Category

Treatment - Drugs

2

Description

Intervention group (B): Recipients of 25 mg/ml topical tranexamic acid in 30 cc normal saline (1 gram in 30 cc normal saline).

Category

Treatment - Drugs

3

Description

Control group: No medication administered.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital, affiliated with Mashhad University of Medical Sciences.

Full name of responsible person

Sina Samiee Rad

Street address

Daneshgah street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

Mohsen Tafaghodi

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Sina Samieerad
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Ear, Nose, and Throat
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Person responsible for scientific inquiries

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Position
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Person responsible for updating data

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Full name of responsible person
Sina Samieerad
Position
Resident
Latest degree
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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
Not applicable
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
The data collected in this study include non-identifiable individual participant information, demographic data, pre- and post-operative bleeding levels, blood test results (CBC), and information related to interventions and postoperative outcomes. All data are stored in a manner that ensures participant anonymity. Raw data may be shared after appropriate de-identification procedures are implemented. Data related to the study's primary outcome, including post-operative bleeding levels and relevant test results, may be shared. However, access to sensitive personal and medical data is restricted to the research team and will be provided only under strict confidentiality protocols.
When the data will become available and for how long
6 months after publishing results
To whom data/document is available
The data from this study will be available only to

researchers working at academic and scientific institutions involved in research related to the study's topic. Data requests must be submitted by verified researchers from reputable institutions and will be evaluated based on their scientific and research objectives. Individuals working in industry or non-scientific organizations must provide sufficient justification and clear research goals in order to request access to the data. Such requests will be considered by the research team, ensuring compliance with ethical standards and data confidentiality protocols. In all cases, adherence to confidentiality principles and the de-identification of individual participant data is mandatory.

Under which criteria data/document could be used

The use of data and documents from this study is permitted only for scientific and research purposes under the following conditions: Specific Research Objectives: Applicants must provide clearly defined research objectives related to the study's topic. These objectives should align with advancing knowledge in the field of head and neck surgeries and the use of tranexamic acid. Permitted Analyses: Permitted analyses include standard statistical analyses to assess postoperative bleeding, comparisons between intervention and control groups, and evaluation of postoperative complications. Any analysis outside the study's original scope requires approval from the research team. No Commercial Use: The data and documents are solely for non-commercial research purposes. Commercial use of the data is strictly prohibited. Confidentiality and Data Security: Non-identifiable individual data must be handled with confidentiality and in accordance with data security protocols. All usage must ensure the privacy and anonymity of the study participants. Formal Request Submission: Requests for data access must be formally submitted, including the applicant's full details, research goals, and a clear description of how the data will be used. Requests should be approved by a recognized academic or scientific institution. Limited to Secondary Analyses: Data and documents may be used for secondary analyses, but any publication or public dissemination of results must be approved in writing by the original research team. Ethical Approval: Any further use of the data must comply with ethical research principles and receive approval from the relevant ethics committees.

From where data/document is obtainable

Responsible for Study Inquiries: Dr. Sina Samiei Rad (phone number: +989921545609)

What processes are involved for a request to access data/document

The request must first be sent to the project response officer, Dr. Sina Samiei Rad, at the email address samiieerads991@mums.ac.ir. Within one week of submitting the request, if there are no legal restrictions, the documents will be made accessible.

Comments