# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

10 Jun 2026

# Evaluating the Efficacy of Topical Tranexamic Acid in Neck Dissection to Reduce Post-Operative Drain Output: A Prospective Randomized Controlled Trial

## Protocol summary

**Study aim**

To evaluate whether topical application tranexamic acid is effective in reducing post-surgical ooze/drain after supraomohyoid neck dissection for oral, head and neck cancer surgeries, thus reducing the length of hospital stay and complications like infection.

**Design**

Two arm parallel group randomized trial with double blinding.Simple randomisation using a randomisation table created by computer software with allocation using concealed envelopes. A sample size of 44 with 22 in the control group and 22 in the study/intervention group at a tertiary care hospital.

**Settings and conduct**

Tertiary care hospital of CMH (Combined Military Hospital) Lahore and CMH Lahore Medical College and Institute of Dentistry

**Participants/Inclusion and exclusion criteria**

Inclusion Criteria: Patients 18 years of age or older, and who agree to participate willing undergoing supraomohyoid neck dissection due to oral, head and neck cancers. Exclusion Criteria: Patients who have a history of hypersensitivity or any adverse reaction to tranexamic acid. Patients having thromboembolic events in the past or any related disorder like DVT, bleeding disorders, who have contraindications to TXA, on anticoagulant or antiplatelet therapy. Patients who do not consent.

**Intervention groups**

The intervention group will get topical tranexamic acid (20ml at 25mg/ml) sprayed over the surgical site of neck dissection, after hemostasis has been achieved. Followed by neck drain placement and neck closure in 2 layers. Control group will not receive this topical tranexamic acid, and neck shall be closed in 2 layers after placement of neck drain.

**Main outcome variables**

Post-operative drainage for the first 24 hrs., first 5 days and the day of removal of drain are the primary outcomes. Whereas the secondary outcomes are surgical site infection (grade of infection), hematoma formation, flap necrosis for neck dissection complications.

## General information

**Reason for update**

After consultation with the hospital's statistician and record manager, the sample size that seems accurate is 44 with 22 in each of the two groups (control group and intervention group)

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20231019059765N1**
Registration date: **2023-12-30, 1402/10/09**
Registration timing: **registered_while_recruiting**

Last update: **2024-03-02, 1402/12/12**
Update count: **1**

**Registration date**

2023-12-30, 1402/10/09

**Registrant information**

**Name**

Muhammad Azhar Imran

**Name of organization / entity**

College of Physicians and Surgeons Pakistan (CPSP Pakistan)

**Country**

Pakistan

**Phone**

+92 321 4267505

**Email address**

azhar.imran1993@gmail.com

**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2023-12-25, 1402/10/04
**Expected recruitment end date**
2024-03-30, 1403/01/11
**Actual recruitment start date**
empty
**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
Evaluating the Efficacy of Topical Tranexamic Acid in Neck Dissection to Reduce Post-Operative Drain Output: A Prospective Randomized Controlled Trial

**Public title**
How effective is tranexamic acid in controlling post-surgical drainage after neck dissection surgery in patients with the oral cancers
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Patients 18 years of age or older Patients who will undergo supraomohyoid neck dissection due to oral, head and neck cancers. Patients who consent to be part of this study, who are willing and able to comply with the protocols of the study.
**Exclusion criteria:**
Patients who have a history of hypersensitivity or any adverse reaction to tranexamic acid or any of its components. Patients having thromboembolic events in the past or any related disorder like pulmonary embolism or DVT. Patients who have bleeding disorders. Patients having contraindications to TXA, such as renal failure/disease or active thromboembolic disease. Patients who are on anticoagulant or antiplatelet therapy that can not be stopped for this surgery. Patients who do not wish to provide informed consent and are unwilling to be part of the study.
**Age**
From **18 years** old
**Gender**
Both

**Phase**
4
**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

**Sample size**
Target sample size: **44**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
Method: Simple Randomization Unit: Individual Stratified randomization Computer randomization using software 2 parallel groups (control group and intervention group) Allocation will be concealed from the patient and principal investigator (assessor) but not from the primary surgeon (Double Blind)
**Blinding (investigator's opinion)**
Double blinded
**Blinding description**
After taking patient consent, they'd be randomly sampled using computer software and handed a sealed envelope the receptionist. The patient shall be blind to whether he has been placed in intervention or control group. Patient will handover the sealed envelope to the surgeon and his team in Operation Theatre who won't be blind to the random sampling, they'd open the sealed envelope and as per serial number, would know if the patient is in intervention group or control group. The assessor won't be present in the OT operation theater and shall remain blind to sampling. Assessor will remain in ward where the patient shall be transferred and remain admitted after surgery, the assessor will analyze the data. Surgeon shall visit ward daily to ensure patients are stable.
**Placebo**
Not used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Ethical Review Committee, CMH Lahore Medical College and Institute of Dentistry
**Street address**
CMH Lahore Medical College and Institute of Dentistry, Abdur Rehman Road, Lahore Cantt, Pakistan
**City**
Lahore
**Postal code**
54810
**Approval date**
2023-10-27, 1402/08/05
**Ethics committee reference number**
683/ERC/CMH/LMC

## Health conditions studied

### 1

**Description of health condition studied**
Neck Drain output after Tumor Resection and Neck Dissection Surgery for Oral Cance3
**ICD-10 code**

C14

**ICD-10 code description**

Malignant neoplasm of other and ill-defined sites in the lip, oral cavity and pharynx

## Primary outcomes

### 1

**Description**

Post-operative drainage for the first 24 hrs., first 5 days and the day of removal of drain are the primary outcomes

**Timepoint**

First 24 hours following surgery, first 5 days, and day of removal of drain

**Method of measurement**

Measurements in milliliters on vacuum suction drain bottle

## Secondary outcomes

### 1

**Description**

Whereas the secondary outcomes are surgical site infection (grade of infection), hematoma formation, flap necrosis for neck dissection complications.

**Timepoint**

Day 1 to day 5 till drain removal

**Method of measurement**

Clinical Examination and visual analogue scale

## Intervention groups

### 1

**Description**

Intervention group having 22 randomly allocated subjects: After tumor resection and neck dissection (supraomohyoid) A total of 20 ml of Tranexamic Acid (TXA) topical solution will be prepared at a concentration of 25 mg/ml by adding one ampule (5 ml) of TXA (100 mg/ml) to 15 ml of normal saline. After achieving complete hemostasis, following supraomohyoid neck dissection for oral, head and neck cancers, 20 ml of TXA solution will be sprayed on the operated field in the neck, once.Dose: 20 ml of topical tranexamic acid at a dose of 25mg/ml (5ml ampule of tranexamic acid containing 100mg/ml of tranexamic acid, mixed with 15ml of normal saline).Mode: Topical (spray solution) Duration: Once before neck closure.There shall be NO repeated administration.Neck Drain Output shall be monitored hourly and once it is less than 25 ml in 24 hrs, drain shall be removed.After spraying the above-mentioned solution, closed suction drain shall be placed and neck closure shall be done in standard way by suturing it in 2 layers.

**Category**

Treatment - Drugs

### 2

**Description**

Control group: 22 randomly allocated subjects, they will NOT receive topical application of tranexamic acid, instead, after tumor resection and neck dissection, and after achieving hemostasis, neck shall be closed in 2 layers (subcutaneous and cutaneous sutures) after placing vacuum suction neck drain.

**Category**

N/A

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**

CMH Lahore, CMH Lahore Medical College and Institute of Dentistry

**Full name of responsible person**

Dr. Muhammad Azhar Imran

**Street address**

House Address Flat 57-F, Second Floor, Askari 1, Sarfaraz Rafique Road, Lahore cantt

**City**

Lahore Cantonment

**Postal code**

54810

**Phone**

+92 321 4267505

**Email**

azhar.imran1993@gmail.com

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

CMH Lahore Medical College and Institute of Dentistry, Lahore, Pakistan

**Full name of responsible person**

Pror. Dr. Asad Aizaz Chatha

**Street address**

Head of Dept, Oral and Maxillofacial Surgery Department, CMH Lahore Medical College and Institute of Dentistry, Abdur Rehman Road, Lahore Cantt, Punjab, Pakistan

**City**

Lahore

**Postal code**

54810

**Phone**

+92 333 4205802

**Email**

asadchatha@hotmail.com

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**
CMH Lahore Medical College and Institute of Dentistry, Lahore, Pakistan
**Proportion provided by this source**
1
**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**
CMH Lahore Medical College and Institute of Dentistry
**Full name of responsible person**
Muhammad Azhar Imran
**Position**
Post Graduate Trainee/Resident of College of Physicians and Surgeons Pakistan
**Latest degree**
Bachelor
**Other areas of specialty/work**
Dentistry
**Street address**
House Address Flat 57-F, Second Floor, Askari 1, Sarfaraz Rafique Road, Lahore cantt
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**Province**
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## Person responsible for scientific inquiries

**Contact**
**Name of organization / entity**
CMH Lahore Medical College and Institute of Dentistry
**Full name of responsible person**
Muhammad Azhar Imran
**Position**
Post Graduate Trainee/Resident of College of Physicians and Surgeons Pakistan
**Latest degree**
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## Person responsible for updating data

**Contact**
**Name of organization / entity**
CMH Lahore Medical College and Institute of Dentistry
**Full name of responsible person**
Muhammad Azhar Imran
**Position**
Post Graduate Trainee/Resident of College of Physicians and Surgeons Pakistan
**Latest degree**
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**Other areas of specialty/work**
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**Province**
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**Postal code**
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azhar.imran1993@gmail.com

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
No - There is not a plan to make this available
**Justification/reason for indecision/not sharing IPD**
CMH Lahore doesn't allow sharing data of patients
**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**
Undecided - It is not yet known if there will be 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**
Evaluating the Efficacy of Topical Tranexamic Acid in Neck Dissection to Reduce Post-Operative Drain Output:

A Prospective Randomized Controlled Trial

**When the data will become available and for how long**

3 months after publication

**To whom data/document is available**

Principal Investigator and sponsor

**Under which criteria data/document could be used**

Request by email to me (principal investigator)

**From where data/document is obtainable**

Email to the principal investigator (me)

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

Request via email

**Comments**