

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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

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

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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

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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

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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