Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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
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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

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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

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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
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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Person responsible for updating data

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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