

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jun 2026

### Removal of Neck Drain in patients undergoing supraomohyoid lareral Neck Dissection by Comparing the Threshold values of the output volume of the neck drain.

#### Protocol summary

##### Study aim

Till data a limited evidence is available about removal of drain after supra-omohyoid neck dissection (SOND). Drains may be left in patient for longer than necessary, leading to infection, discomfort, longer hospital stay and costs.

##### Design

Two arm parallel group randomized trial with single blinding. Simple randomisation using a randomisation table created by computer software with allocation using concealed envelopes. A sample size of 82 with 41 in the control group and 41 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

Consenting Patients between the age of 30 to 65 years of age shall be included. Patients to be excluded would be the ones having hypertension, cardio-pulmonary illnesses, renal and hepatic illnesses, anemia, obesity, free flap surgeries and paralyzed.

##### Intervention groups

On the first postsurgical day, patients shall randomized to either a drain removal threshold of less than 30 mL or less than 100 mL during a 24-hour period

##### Main outcome variables

Drain use duration, hospitalization duration, and wound complications such as infection and seroma for both groups.

#### General information

##### Reason for update

Sample size is 82, with 41 in each group, as determined by the institution's statistician

#### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20231019059765N2**

Registration date: **2024-07-20, 1403/04/30**

Registration timing: **registered\_while\_recruiting**

Last update: **2024-09-24, 1403/07/03**

Update count: **5**

##### Registration date

2024-07-20, 1403/04/30

##### 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

2024-01-03, 1402/10/13

##### Expected recruitment end date

2024-08-13, 1403/05/23

##### Actual recruitment start date

2024-01-03, 1402/10/13

##### Actual recruitment end date

2024-08-13, 1403/05/23

##### Trial completion date

2024-08-13, 1403/05/23

## Scientific title

Removal of Neck Drain in patients undergoing supraomohyoid lareral Neck Dissection by Comparing the Threshold values of the output volume of the neck drain.

## Public title

Removal of Neck Drain in patients undergoing supraomohyoid lareral Neck Dissection by Comparing the Threshold values of the output volume of the neck drain.

## Purpose

Supportive

## Inclusion/Exclusion criteria

### Inclusion criteria:

Patients 30 years of age or older upto 65 years of age, and need neck dissection due to oral, head and neck cancers. Patients who agree to participate willingly under going supraomohyoid neck dissection

### Exclusion criteria:

Hypertensive patient Bleeding Disorders Renal disorders Hepatic disorders Any Cardiac/Heart related disease or illness History of thromboembolic disorders or DVT Anemic patients Obesity with BMI 30.0 and Above Paralyzed patients who can not walk Patient requiring free flap surgeries

## Age

From **30 years** old to **65 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

- Participant
- Data analyser
- Data and Safety Monitoring Board

## Sample size

Target sample size: **82**

Actual sample size reached: **82**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Method: Simple Randomization Unit: Individual Stratified randomization Computer randomization using software TWO parallel groups (control group and intervention group) Allocation will be concealed from the patient and principal investigator (assessor) but not from the primary surgeon (single Blind)

## Blinding (investigator's opinion)

Single 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 may be present in the OT operation theater. Assessor and the Operating Surgeon 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

Abdur Rehman Road, Lahore Cantt

##### City

Lahore

##### Postal code

54000

#### Approval date

2023-10-27, 1402/08/05

#### Ethics committee reference number

Case .684/ERC/CMH/LMC

## Health conditions studied

### 1

#### Description of health condition studied

Oral cancer

#### 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

Time for which the neck drain will remain in place, neck drain in milliliters, length of hospital stay, infection, seroma formation

#### Timepoint

Post-operatively day 1, 2, 3, 4, 5, 6, and 7.

#### Method of measurement

Collection of neck drain amount in closed suction drain bottle in millimeters. Redness, swelling, pus discharge, number of days for hospital stay

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Control group: In this group the neck drain shall be removed when it is at 24ml in 24 hrs. or less (as is the standard procedure in most centers) after Supraomohyoid Neck dissections (SOND) in patients with oral cancers.

#### Category

Prevention

### 2

#### Description

Intervention group: In this group the neck drain shall be removed when it is at 100ml in 24 hrs.(to reduce hospital stay and see if it reduces chances of infection, seroma formation and costs) after Supraomohyoid Neck dissections (SOND) in patients with oral cancers.

#### Category

Prevention

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

CMH Lahore Medical College and Institute of Dentistry, CMH Lahore

##### Full name of responsible person

CMH Lahore Medical College and Institute of Dentistry, CMH Lahore

##### Street address

Abdur Rehman Road, Lahore Cantt

##### City

Lahore

##### Postal code

54000

##### Phone

+92 321 4267505

##### Email

azhar.imran1993@gmail.com

##### Web page address

<https://cmhlahore.edu.pk/>

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Combined Military Hospital (CMH) Lahore Medical College

##### Full name of responsible person

Muhammad Azhar Imran

##### Street address

Dr. Azhar Imran, Oral & Maxillofacial Surgery Dept. Institute of Dentistry, CMH Lahore Medical College

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<https://cmhlahore.edu.pk/>

#### Grant name

Self financing by authors/surgical team; Dr. Muhammad Azhar Imran; Dr. Bareerah Idrees; Brig. Dr. Babar Pasha; Dr. Vaffa Shahid Khan; Capt. Dr. Muhammad Ali Shuja; Dr. Zahra Saeed Seethi

#### Grant code / Reference number

Self financing by authors/surgical team; Dr. Muhammad Azhar Imran; Dr. Bareerah Idrees; Brig. Dr. Ba

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

No

#### Title of funding source

All six authors of this Randomized Controlled Clinical Trial, self-financed this trial, they worked hard and tirelessly with their own abilities and funding for the success and completion of this Randomized Controlled Clinical Trial; their names are as fo

#### Proportion provided by this source

100

#### Public or private sector

Private

#### Domestic or foreign origin

Domestic

#### Category of foreign source of funding

*empty*

#### Country of origin

#### Type of organization providing the funding

Persons

## Person responsible for general inquiries

#### Contact

##### Name of organization / entity

Oral & Maxillofacial Surgery Dept., CMH Lahore Medical College and Institute of Dentistry

##### Full name of responsible person

Muhammad Azhar Imran

##### Position

Post Graduate FCPS-II Trainee

##### Latest degree

Medical doctor

##### Other areas of specialty/work

Dentistry

##### Street address

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

##### City

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##### Province

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##### Postal code

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

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**Full name of responsible person**

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**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

**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**

Oral & Maxillofacial Surgery, Head and Neck Surgery

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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**

Privacy patient laws of Combined Military Hospital Lahore

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

No - There is not 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**

Original Article, Manuscript, Data, Ethical Review Committee Form, Acceptance Letter for Article Publications

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

After publication and indefinitely

**To whom data/document is available**

Editor and team of the Journal

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

Main Author (me) by emailing me at azhar.imran1993@gmail.com

**From where data/document is obtainable**

Main Author (me) by emailing me at azhar.imran1993@gmail.com

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

Main Author (me) by emailing me at azhar.imran1993@gmail.com

**Comments**

All six authors of this Randomized Controlled Clinical Trial, self-financed this trial, they worked hard and tirelessly with their own abilities and funding for the success and completion of this Randomized Controlled Clinical Trial; their names are as follow; Dr. Muhammad Azhar Imran; Dr. Bareerah Idrees; Brig. Dr. Babar Pasha; Dr. Vaffa Shahid Khan; Capt. Dr. Muhammad Ali Shuja; Dr. Zahra Saeed Seethi