Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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
City
Lahore Cantonment
Postal code
54810
Phone
+92 321 4267505
Email
azhar.imran1993@gmail.com
Web page address
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
Lahore Cantonment
Province
Punjab
Postal code
54810
Phone

+92 321 4267505

Email

azhar.imran1993@gmail.com

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

Bachelor

Other areas of specialty/work

Dentistry

Street address

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

City

Lahore Cantonment

Province

Punjab

Postal code

54810

Phone

+92 321 4267505

Email

azhar.imran1993@gmail.com

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 & Maxillofacail Surgery, Head and Nexk Surgery

Street address

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

City

Lahore Cantonment

Province

Punjab

Postal code

54810

Phone

+92 321 4267505

Email

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

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