

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Randomised Clinical Trial on scalpel versus diathermy skin incision in maxillofacial surgery.

#### Protocol summary

##### Study aim

This study aims provide evidence about the most suitable tool to be used in oral and maxillofacial surgery for skin incisions in terms of incisional time, intraoperative blood loss due to incision, post-operative skin incision site pain occurring from both methods of skin incision.

##### 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 82 with 41 in scalpel group and 41 in diathermy group at a tertiary care hospital.

##### Settings and conduct

At Combined Military Hospital Lahore and CMH Lahore Medical College and IOD

##### Participants/Inclusion and exclusion criteria

Inclusion Criteria: Patients of any gender, within the age limit of 30-60 years, who underwent maxillofacial surgery including neck dissections, parotid surgery and maxillofacial trauma. Incision size between 2 to 10 cm will be included. Exclusion Criteria: patients with signs of active wound infection and anaemia. Patients on anticoagulant or corticosteroid therapy, patients who already have an existing scar on the probable incision site. patients with known connective tissue disorder and predilection of keloid scars

##### Intervention groups

Incision shall be made using scalpel in scalpel group and diathermy for Incision in the diathermy group. Incision for maxillofacial surgery

##### Main outcome variables

Incision time during surgery, Perop blood loss measured during surgery, pain using visual analogue scale during patient follow ups for the next 3 months

#### General information

##### Reason for update

##### Acronym

Not applicable

##### IRCT registration information

IRCT registration number: **IRCT20240101060587N1**

Registration date: **2024-01-28, 1402/11/08**

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

Last update: **2024-01-28, 1402/11/08**

Update count: **0**

##### Registration date

2024-01-28, 1402/11/08

##### Registrant information

##### Name

Vaffa Khan

##### Name of organization / entity

College of Physicians and Surgeons Pakistan

##### Country

Pakistan

##### Phone

+92 321 4481828

##### Email address

vaffasaad@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2024-01-15, 1402/10/25

##### Expected recruitment end date

2024-02-15, 1402/11/26

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Randomised Clinical Trial on scalpel versus diathermy skin incision in maxillofacial surgery.

## Public title

To determine which surgical tool is better for skin incisions in maxillofacial surgeries, whether it's scalpel or diathermy

## Purpose

Education/Guidance

## Inclusion/Exclusion criteria

### Inclusion criteria:

Age 30 years old to 60 years old Maxillofacial region surgery including tumor resection, neck dissection, parotid surgery, Maxillofacial trauma surgery Incision length 2 cm to 10 cm Patients who give consent

### Exclusion criteria:

Patients who have active wound infections, anemia Patients who are on corticosteroids, anticoagulant, anti platelet medication Any previous scar or keloid Patients with known connective tissue and skin disorders

## Age

From **30 years** old to **60 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

## Sample size

Target sample size: **82**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Method: Simple Randomization Unit: Individual Stratified randomization Computer randomization using software 2 parallel groups (both would be intervention groups) 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

Patients will provide consent to be part of the trial. After which they would be randomized using computer software into two parallel intervention groups. Patients won't be aware of the group they belong to. They would be handed sealed envelope of their id number, only the surgeon and his/her operation theatre team would know the group to which the patient would belong to and they would record their findings against patients ID number without mentioning the group of the patient (whether scalpel group or diathermy group). The post surgery assessor and ward staff would also be blind to the randomization. So, in short, Patients will be randomly assigned into two mutually exclusive groups each experiencing a different incision tool. The two groups will

be scalpel group and diathermy group. Randomly, a sealed card with either scalpel or diathermy incision option inside, will be drawn, to decide which tool will be applied. The surgeon performing the incision shall not be blinded, however the patient and the assessor will be blind to the incision tool used.

## Placebo

Not used

## Assignment

Parallel

## Other design features

Sample size of 82 (with 41 participants in each group)

## 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

2024-01-12, 1402/10/22

#### Ethics committee reference number

.05/ERC/CMH/LMC12-01-24

## Health conditions studied

### 1

#### Description of health condition studied

Incision time, intraoperative bleeding from Incision and post surgical pain after Incision using scalpel or diathermy

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Incision Time

#### Timepoint

Incision Time (time taken from the initial skin incision till end of incision), will be noted and calculated in seconds per unit wound area (sec/cm<sup>2</sup>).

#### Method of measurement

Stop watch

## 2

### **Description**

Intraoperative blood loss

### **Timepoint**

Intraoperative blood loss will be measured from the point when incision begins to the point patient is shifted out of the operation theater to the ward and eventually discharged from the ward. Every 6 hours after the surgery till the patient is discharged from the hospital (day 2 to day 6)

### **Method of measurement**

Intraoperative blood loss will be measured by weighing the total weight of blood-soaked gauze from the patients

## 3

### **Description**

Pain

### **Timepoint**

Regular follow up with the patients will be carried out, every 6 hours post surgery on day 1 and day 2, daily for the next five days, at one week- for assessment of acute pain if any, 4 weeks, and 3 months- for assessment of chronic pain if any.

### **Method of measurement**

Visual analogue scale for pain

## **Secondary outcomes**

empty

## **Intervention groups**

## 1

### **Description**

Intervention group: Scalpel Incision Group. No. 15 disposable scalpel with no.3 reusable sterilizable handles. Skin incisions, mucosal incisions would be larger than 2 cm in maxillofacial region. incisional time and intraoperative blood loss during incision shall be calculated during the surgery, for post-operative skin incision site pain, regular follow up with patients will be carried out over a period of three months to determine extent of postoperative pain. Prospective data will be collected in quantitative form. post-op visits (upto 3 months). Regular follow up with the patients will be carried out daily for five days, at one week- for assessment of acute pain if any, 4 weeks, and 3 months- for assessment of chronic pain if any.

### **Category**

Treatment - Surgery

## 2

### **Description**

Intervention group: Diathermy group. Incisions on skin and mucosal layers of maxillofacial region made using diathermy using Monopolar and Bipolar cautery at 0.5 to 3 MHz. incisional time and intraoperative blood loss during incision shall be calculated during the surgery, for post-operative skin incision site pain, regular follow up

with patients will be carried out over a period of three months to determine extent of postoperative pain. Prospective data will be collected in quantitative form. post-op visits (upto 3 months). Regular follow up with the patients will be carried out daily for five days, at one week- for assessment of acute pain if any, 4 weeks, and 3 months- for assessment of chronic pain if any.

### **Category**

Treatment - Surgery

## **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. Vaffa Shahid Khan

#### **Street address**

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**

+92 321 4481828

#### **Email**

vaffasaad@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**

Prof. 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**

Dr. Vaffa Shahid Khan

**Position**

Post Graduate Trainee/Resident of College of  
Physicians and Surgeons Pakistan

**Latest degree**

Bachelor

**Other areas of specialty/work**

Dentistry

**Street address**

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

**City**

Lahore

**Province**

Punjab

**Postal code**

54810

**Phone**

+92 321 4481828

**Email**

vaffasaad@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**

Dr. Vaffa Shahid Khan

**Position**

Post Graduate Trainee/Resident of College of  
Physicians and Surgeons Pakistan

**Latest degree**

Bachelor

**Other areas of specialty/work**

Dentistry

**Street address**

Oral and Maxillofacial Surgery Department, CMH

Lahore Medical College and Institute of Dentistry,  
Abdur Rehman Road, Lahore Cantt, Punjab, Pakistan

**City**

Lahore

**Province**

Punjab

**Postal code**

54810

**Phone**

+92 321 4481828

**Email**

vaffasaad@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**

Dr. Vaffa Shahid Khan

**Position**

Post Graduate Trainee/Resident of College of  
Physicians and Surgeons Pakistan

**Latest degree**

Bachelor

**Other areas of specialty/work**

Dentistry

**Street address**

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

**City**

Lahore

**Province**

Punjab

**Postal code**

54810

**Phone**

+92 321 4481828

**Email**

vaffasaad@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**

Randomised Clinical Trial on scalpel versus diathermy skin incision in maxillofacial surgery

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

3 months after the publication

**To whom data/document is available**

Principal Investigator and sponsor

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

Email to the principal investigator (me)

**From where data/document is obtainable**

Email to the principal investigator (me)

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

Email to the principal investigator (me)

**Comments**