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 om 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
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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 operatiom 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/cm2).

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
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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

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

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

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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

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