Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

comparative study of diode laser and scalpel surgery in oral mucosal lesions

Protocol summary

Study aim
To compare the post-operative pain during the procedure along with bleeding and time duration of the procedure

Design
this study was designed as a prospective, randomized, controlled, participant blinded trail comparing diode laser assisted oral mucosal biopsy with conventional scalpel biopsy.

Settings and conduct
the study was conducted in Oral and maxillofacial surgery department of foundation university college of dentistry. ethical approval was attained by the institutional review board.

Participants/Inclusion and exclusion criteria
inclusion: age range (18-65 years) patient with any oral mucosal lesions lesion of greater than 1 cm in diameter exclusion criteria: patient with systemic diseases affecting wound healing individuals receiving anticoagulation or antiplatelet therapy

Intervention groups
group 1 (diode laser) group 2 (scalpel surgery)

Main outcome variables
post operative pain experienced by the patient 30 min after the procedure on the day of procedure

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20261002071256N1**
Registration date: **2026-10-08, 1405/07/16**
Registration timing: **retrospective**

Last update: **2026-10-08, 1405/07/16**
Update count: **0**

Registration date
2026-10-08, 1405/07/16

Registrant information

Name
maidah hanif

Name of organization / entity
Foundation University College of Dentistry and Hospital

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Pakistan

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md7534@hotmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-06-01, 1404/03/11

Expected recruitment end date
2026-01-01, 1404/10/11

Actual recruitment start date
2025-06-01, 1404/03/11

Actual recruitment end date
2026-01-01, 1404/10/11

Trial completion date
2026-01-10, 1404/10/20

Scientific title
comparative study of diode laser and scalpel surgery in oral mucosal lesions

Public title
comparative study of diode laser and scalpel surgery in oral mucosal lesions

Purpose
Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria:
patient with any mucosal lesions patient requiring oral mucosal biopsy for diagnostic purpose lesion of greater than 1cm in diameter both genders of age ranging from

18- 65 years old

Exclusion criteria:

patient with systemic diseases affecting wound healing. individuals receiving anticoagulation or antiplatelet therapy

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

1

Groups that have been masked

- Participant

Sample size

Target sample size: **60**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

simple randomization individuals two strata group 1 with diode laser and group 2 with scalpel surgery lottery method for randomization

Blinding (investigator's opinion)

Single blinded

Blinding description

participants were blinded in this study; we did not tell the participants that which technique they will be receiving as a mean of procedure and were randomly allocated to one of the two established surgical techniques for biopsy

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

foundation university medical college

Street address

DHA phase 1, Jinnah avenue

City

Islamabad

Postal code

44000

Approval date

2024-11-11, 1403/08/21

Ethics committee reference number

FF/FUMC/215-538/Phy/24

Health conditions studied

1

Description of health condition studied

oral mucosal lesions

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

diode laser is superior to scalpel biopsy because of shorter time required to perform the procedure, less intraoperative bleeding and reduced pain after the procedure

Timepoint

6 months

Method of measurement

visual analogue scale for pain, time during of the procedure in minutes and presence bleeding

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: group A for laser diode biopsies and group B for scalpel biopsies

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Foundation university college of dentistry

Full name of responsible person

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Sponsors / Funding sources

1

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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
foundation university islmabad
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
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
foundation university islamabad
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Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
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
Yes - There is 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
complete details of results of the study with statistics
When the data will become available and for how long
on request/ for 1 year
To whom data/document is available
any person interested in our trail / research
Under which criteria data/document could be used
for research pubblicato
From where data/document is obtainable
email
What processes are involved for a request to access data/document
e-mail to the corresponding person
Comments