Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of the Effect of Two Wavelengths (660 nm and 808 nm) of Diode Laser (LLLT) on Bacterial Load and Healing of Oral Biopsy Site

Protocol summary

Study aim

Compare the effects of ۶۶۰ nm and ۸۰۸ nm diode laser LLLT on reducing bacterial load and enhancing clinical wound healing in intraoral biopsy sites.

Design

A randomized, double-blind, parallel-group clinical trial with a control arm involving 30 patients. Block randomization was used for allocation.

Settings and conduct

Location: Department of Oral Medicine, Shiraz University of Medical Sciences Population: Adults aged 18–65 with exophytic oral lesions (<2×2 cm) Procedure: Excisional biopsy under local anesthesia Block randomization (blocks of 4), stratified by age and biopsy site Follow-ups on days 7 and 14 to assess bacterial load and wound healing score (EHS) Blinding: Participants blinded using a sham laser device Laser operator and clinical/microbial outcome assessors blinded to group allocation

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Adults aged ۱۸–۶۵ requiring excisional biopsy of exophytic oral lesions Lesion size: < ۲ cm × ۲ cm (measured with calipers). Willingness to attend follow-ups (days ۷ and ۱۴). Exclusion Criteria: History of oral cancer, lupus, epilepsy, or pregnancy. Immunosuppression (HIV, chemotherapy, corticosteroids). systemic diseases impairing healing (e.g., uncontrolled diabetes). Recent antibiotic/anti-inflammatory use (<۴ weeks).

Intervention groups

Group A: Standard care + sham laser Group B: Standard care + 660 nm LLLT Group C: Standard care + 808 nm LLLT

Main outcome variables

Reduction of bacterial load at three time points (baseline, immediately after laser therapy, and 7 days post-biopsy) measured in CFU/mL; clinical wound healing assessment using the Early Healing Score (EHS) at the same time points.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130521013406N6**
Registration date: **2026-05-14, 1405/02/24**
Registration timing: **registered_while_recruiting**

Last update: **2026-05-14, 1405/02/24**
Update count: **0**

Registration date

2026-05-14, 1405/02/24

Registrant information

Name

Fahimeh Rezazadeh

Name of organization / entity

Dental school of shiraz university of medical science

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-09-23, 1404/07/01

Expected recruitment end date

2026-09-23, 1405/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of the Effect of Two Wavelengths (660 nm and 808 nm) of Diode Laser (LLLT) on Bacterial Load and Healing of Oral Biopsy Site

Public title
Evaluation of 660-nm and 808-nm Laser Therapy for Reducing Microbial Load and Healing Oral Biopsy Wounds

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
adults aged ۱۸–۶۵ requiring excisional biopsy of exophytic oral lesions Lesion size: < ۲ cm × ۲ cm (measured with calipers) Willingness to attend follow-ups (days ۷ and ۱۴)

Exclusion criteria:
History of oral cancer, lupus, epilepsy, or pregnancy Immunosuppression (HIV, chemotherapy, corticosteroids) systemic diseases impairing healing (e.g., uncontrolled diabetes) Recent antibiotic/anti-inflammatory use (<۴ weeks)

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

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
Block randomization will be employed to ensure balance across age groups (۱۸–۴۰ vs. ۴۱–۶۵ years) and biopsy site locations. After selecting patients who met the inclusion criteria for the study and providing a complete explanation of the objectives of the research project, an informed consent form will be completed for all of them. Subsequently, patients will be divided into ۳ groups using random blocks of ۴. Group A will receive a placebo (sham laser) group B will be received ۶۶۰ nm lased and group C will be received ۸۰۸ nm laser.

Blinding (investigator's opinion)
Double blinded

Blinding description
Participants will be blinded through the use of a sham laser device that mimics the appearance and sound of the active laser units but emits no therapeutic light. clinical evaluators will remain blinded to group allocation.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences

Street address
Central building of Shiraz University of Medical Sciences Zand St.

City
Shiraz

Province
Fars

Postal code
7134814336

Approval date
2026-05-10, 1405/02/20

Ethics committee reference number
IR.SUMS.REC.1405.125

Health conditions studied

1

Description of health condition studied
Exophytic oral lesions

ICD-10 code

ICD-10 code description
Exophytic oral lesions

Primary outcomes

1

Description
Primary Outcome Variable 1: Bacterial load at the biopsy site (colony-forming units per milliliter). This outcome measures the quantitative change in bacterial presence at the biopsy site over time. Bacterial load is assessed through sterile swab sampling followed by aerobic and anaerobic culture. The number of colony-forming units per milliliter is calculated using serial dilution plating on blood agar and incubated at 37°C for 24 to 48 hours. A decrease in CFU/mL over time is interpreted as effective bacterial reduction due to the intervention.

Timepoint
Bacterial load (colony-forming units per milliliter): Measured at three time points: Before the start of laser therapy (baseline), Immediately after completion of laser therapy, Seven days after the biopsy procedure

Method of measurement
Sterile swab sampling from the biopsy site; culture on blood agar under aerobic and anaerobic conditions; colony-forming units per milliliter determined by serial dilution plating. Incubation is performed at 37 degrees Celsius for 24 to 48 hours before bacterial

quantification./

2

Description
Primary Outcome Variable 2: Clinical wound healing score based on the Early Healing Score outcome evaluates the clinical healing process at the biopsy site using the Early Healing Score, a validated composite index. It includes three components: re-epithelialization, hemostasis, and inflammation. Each component is scored separately and summed to produce a total score ranging from 0 (poor healing) to 10 (ideal healing). The assessment is performed at multiple time points by a blinded clinical evaluator.

Timepoint
Wound healing score (Early Healing Score): Measured at three time points: Immediately after laser therapy Seven days after the biopsy Fourteen days after the biopsy

Method of measurement
Clinical assessment form based on the Early Healing Score index, evaluating three parameters: re-epithelialization, hemostasis, and inflammation. Scoring is performed by a trained and blinded clinical evaluator using a validated wound healing scale.

Secondary outcomes

1

Description
Secondary Outcome Variable 1: Postoperative pain intensity measured by Visual Analogue Scale (VAS)Postoperative pain will be measured using the Visual Analogue Scale, a 100-mm horizontal line anchored at each end by descriptors: "no pain" (0 mm) on the left and "worst imaginable pain" (100 mm) on the right. Patients will mark the point that best represents their perceived pain intensity, and the distance in millimeters from the left end will be recorded. Pain assessments will be conducted at baseline (before treatment) and on postoperative days 1, 3, 7, and 14.

Timepoint
For postoperative pain (Visual Analogue Scale): Before intervention (baseline), Postoperative day 1, Postoperative day 3, Postoperative day 7, Postoperative day 14

Method of measurement
Visual Analogue Scale: a 100-mm horizontal line anchored at each end by descriptors: "no pain" (0 mm) on the left and "worst imaginable pain" (100 mm) on the right. Patients will mark the point that best represents their perceived pain intensity, and the distance in millimeters from the left end will be recorded. Pain assessments will be conducted at baseline (before treatment) and on postoperative days 1, 3, 7, and 14.

2

Description
Secondary Outcome Variable 2: Patient satisfaction with wound healing measured by a 5-point Likert scale.

Timepoint
Patient satisfaction regarding the wound healing process will be assessed on postoperative day 14 using a 5-point Likert scale.

Method of measurement
Participants will choose one of the following options = Very dissatisfied, 2 = Dissatisfied, 3 = Neutral, 4 = Satisfied, 5 = Very satisfied. Results will be reported as the percentage of participants in each category, particularly those selecting “satisfied” or “very satisfied,” across the three study groups.

Intervention groups

1

Description
Intervention group: 660 nm diode laser therapy (100 milliwatt, 4 joules/cm² energy density, continuous wave mode, 60 seconds per site) using XYZ Medical Lasers Model LLLT-3000 + Standard care (normal saline rinse).

Category
Treatment - Devices

2

Description
Intervention group: 808 nm diode laser therapy (100 milliwatt, 4 joules/cm² energy density, continuous wave mode, 60 seconds per site) using XYZ Medical Lasers Model LLLT-3000 + Standard care (normal saline rinse).

Category
Treatment - Devices

3

Description
Control group: Sham laser (inactive device: XYZ Medical Lasers Model LLLT-3000) + Standard care (0.9% normal saline mouth rinse twice daily for 7 days post-biopsy).

Category
Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center
School of Dentistry

Full name of responsible person
Fahimeh Rezazadeh

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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
Shiraz University of Medical Sciences
Proportion provided by this source
100
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
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Full name of responsible person
Fahimeh Rezazadeh
Position
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Latest degree
Specialist
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

Study Protocol

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be 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