

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jul 2026

The effect of low level laser on tooth sensitivity after orthodontic resection

Protocol summary

Study aim

The effect of low level laser on tooth sensitivity after orthodontic resection.

Design

This study is a randomized clinical trial with a parallel design and a control group. This randomized study will be performed on 28 patients. For randomization, Random numbers will be generated online and participants are assigned to two intervention groups and one control group.

Settings and conduct

This study, which will be performed in the specialized dental clinic of Kermanshah University of Medical Sciences, is double-blind. In this double-blind study, researchers and patients are kept blind as to what type of treatment they will receive. Also, researchers and participants have no role in the process of randomization and assignment of intervention groups. At each point, the surface of the mucosa dries, and the laser probe, which is covered with disposable nylon foam, adheres vertically to the mucosa and presses until the mucosa surface is partially white.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age between 18 to 22 years; Informed consent; People who needed orthodontics. Exclusion criteria: Dependence on psychotropic drugs; History of anticonvulsant and antidepressant use; Chronic systemic diseases such as liver, lung, heart and kidney diseases etc...; History of neuropathic disorders

Intervention groups

The first intervention group will receive a 200-wavelength laser (at each buccal or lingual surface, two dots, one 5 mm from the gingival margin and one point near the apex, apply the laser probe for 4 seconds). The second intervention group will receive a laser with a wavelength of 300 (in each buccal or lingual surface, two points, one at a distance of 5 mm from the gingival margin and one point near the apex, the laser probe is applied for 4 seconds). The control group will not receive

a laser.

Main outcome variables

Tooth sensitivity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130812014333N181**

Registration date: **2022-02-09, 1400/11/20**

Registration timing: **prospective**

Last update: **2022-02-09, 1400/11/20**

Update count: **0**

Registration date

2022-02-09, 1400/11/20

Registrant information

Name

Feizollah Foroughi

Name of organization / entity

kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 83 1821 4653

Email address

fforoughi@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-02-28, 1400/12/09

Expected recruitment end date

2022-05-30, 1401/03/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of low level laser on tooth sensitivity after orthodontic resection

Public title

The effect of low level laser on tooth sensitivity

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age between 18 to 22 years Informed consent People who needed orthodontics.

Exclusion criteria:

Dependence on psychotropic drugs and narcotics History of taking anticonvulsants and antidepressants History of chronic systemic diseases such as liver, lung, heart and kidney diseases, etc. History of neuropathic disorders, glossopharyngeal neuralgia, etc. Diabetes and metabolic diseases

Age

From **18 years** old to **22 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **28**

Randomization (investigator's opinion)

Randomized

Randomization description

Production of random numbers online in Kitset Website. Divided quadrants will be drawn on 28 sheets of paper (in the number of patients) and random numbers will be written on each quadrant. Then, each of the papers will be placed in an envelope. Each patient removes an envelope and based on that, the method of placement of elastic separator will be done in each quadrant. The production of random numbers and allocation concealment will be done by an impartial observer.

Blinding (investigator's opinion)

Double blinded

Blinding description

Laser light with a wavelength of 940 nm is not visible to the human eye and no heat is generated. Therefore, both the patient and the operator were blind (on or off) when using the laser. The laser radiation will be performed by the dentist's assistant. The operator will not know which quadrant is treated with the laser on and which is treated with the laser off. However, complete blinding of the patient will not be possible, and only blinding for laser on or off will be possible.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Kermanshah University of Medical Sciences

Street address

Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti Boulevard

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Approval date

2022-01-10, 1400/10/20

Ethics committee reference number

IR.KUMS.REC.1400.756

Health conditions studied**1****Description of health condition studied**

Orthodontic pain

ICD-10 code

Z51.8

ICD-10 code description

Encounter for other specified aftercare

Primary outcomes**1****Description**

Tooth sensitivity

Timepoint

6 days after the start of the intervention

Method of measurement

Inspection

Secondary outcomes

empty

Intervention groups**1****Description**

The first intervention group will receive a 200-wavelength laser (at each buccal or lingual surface, two dots, one 5 mm from the gingival margin and one point near the apex, apply the laser probe for 4 seconds).

Category

Treatment - Other

2

Description

The second intervention group will receive a laser with a wavelength of 300 (in each buccal or lingual surface, two points, one at a distance of 5 mm from the gingival margin and one point near the apex, the laser probe is applied for 4 seconds).

Category

Treatment - Other

3

Description

The control group will not receive a laser.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Specialized clinic of the School of Dentistry

Full name of responsible person

Dr. Navid Razaei

Street address

Faculty of Dentistry, Shariati Ave

City

Kermanshah

Province

Kermanshah

Postal code

6713954658

Phone

+98 83 3729 6591

Email

navidrezaie24@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Reza Khodarahmi

Street address

Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti Boulevard

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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

Kermanshah 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

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Navid Razaei

Position

Faculty member of Kermanshah University of Medical Sciences

Latest degree

Specialist

Other areas of specialty/work

Orthodontist

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

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Person responsible for updating data**Contact****Name of organization / entity**

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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

There is no more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available