

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

Comparing low level laser therapy and laser acupuncture effects on reducing pain in orthodontic patients

Protocol summary

Study aim

Evaluation of the effects of low-level laser therapy and laser acupuncture on reducing orthodontic pain

Design

This clinical trial has 2 intervention groups and 1 control group. The trial will be one-way blind, randomized, phase 2 and on 45 people. Patients will be randomly divided into one of three groups using triple blocks.

Settings and conduct

In this study, patients referred to private clinics of Birjand who are undergoing orthodontic treatment will be invited to participate in the trial. This study will be a single-blind randomized clinical trial in which patients will not be informed whether they are in the treatment or placebo group.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients who are treated for the first time using a fixed appliance; Had no systemic diseases; Had fully erupted permanent teeth; Had no chronic or neural pain. The exclusion criteria: Patients who are pregnant; patients who use systemic medications (analgesics, antibiotics, anti-inflammatory drugs, antidepressants, and bisphosphonates); patients with pathological conditions associated with teeth, gingiva, or periodontium.

Intervention groups

Intervention group 1 (low level laser therapy): A Simpler2 diode laser will be used for patients in this group.
Intervention group 2 (acupuncture laser therapy): A Wiser 3 diode laser will be used for patients in this group.
Control group: The laser device will be in the same position as the previous two groups, except that the device will be off.

Main outcome variables

Orthodontic treatment pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210514051292N1**

Registration date: **2022-05-11, 1401/02/21**

Registration timing: **registered_while_recruiting**

Last update: **2022-05-11, 1401/02/21**

Update count: **0**

Registration date

2022-05-11, 1401/02/21

Registrant information

Name

Behzad Ghadiri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 26 3650 8135

Email address

behzad.ghadiri.14@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-21, 1401/02/01

Expected recruitment end date

2022-09-21, 1401/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing low level laser therapy and laser acupuncture effects on reducing pain in orthodontic patients

Public title

Investigating the effect of laser in orthodontics

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients that are treated for the first time using a fixed orthodontic appliance. Having no systemic diseases. Having fully erupted permanent teeth. Having no chronic or neural pain.

Exclusion criteria:

Patients who are pregnant. Patients who use systemic medications (analgesics, antibiotics, anti-inflammatory drugs, antidepressants, and bisphosphonates). Patients with pathological conditions associated with teeth, gingiva, or periodontium.

Age

From **18 years** old to **40 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients with the above conditions were divided into three groups randomly and by blocking method (blocks of size 3) into one of three groups: intervention 1 and intervention 2 or control. Patients were divided into three groups: Simpler2 diode laser as group A, Wiser 3 laser diode as group B and control group as group C. First, various blocks of size 3 were created (ABC, ACB, BAC, BCA, CAB, CBA). One of these blocks was randomly selected and divided into one of three groups A, B or C according to the order mentioned in the patients' selected block. Then randomization was performed for other patients.

Blinding (investigator's opinion)

Single blinded

Blinding description

This study is single-blinded in which patients are unaware that they are receiving laser therapy or placebo. In both treatment groups and placebo, the laser is placed in the same way and with the same specifications in the desired points, and the light and sound of the laser beep are on for both groups, but the radiation is done only for the treatment group.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Birjand University of Medical Sciences

Street address

Birjand University of Medical Sciences, Moalem street, Birjand

City

Birjand

Province

South Khorasan

Postal code

9717853577

Approval date

2021-10-09, 1400/07/17

Ethics committee reference number

IR.BUMS.REC.1400.206

Health conditions studied

1

Description of health condition studied

Pain in orthodontics

ICD-10 code

G89

ICD-10 code description

Pain, not elsewhere classified

Primary outcomes

1

Description

Pain score

Timepoint

Immediately, 6 hours, 12 hours, 1 day, 2 days, 3 days, 4 days and 5 days after orthodontic applique placement.

Method of measurement

Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: For patients in this group, a Simpler2 diode laser (Doctor Smile Simpler, made in Italy) with a wavelength of 980 nm with a biomodeling handpiece will be used with the following parameters: 1 watt output energy, 1 cm square cross-sectional area, continuous mode), Dose 150 joules per square centimeter, time 150 seconds in total. The laser diode will be in contact with the soft tissue.

Category

Treatment - Other

2**Description**

Intervention group 2: For patients in this group, a Wiser 3 diode laser (Doctor Smile, made in Italy) with a wavelength of 808 nm with a biomodeling handpiece with the following parameters will be used: 200 mW output energy, 0.28 cm cm cross-sectional area, continuous mode continuous), energy dose 21 joules per square centimeter, time 30 seconds at each point, 8 points (points sl18-st6-st7-li4 on both sides), total time 4 minutes. The diode laser will be used in contact with the tissue.

Category

Treatment - Other

3**Description**

Control group: For this group, the device is kept in the same position as the previous groups for patients, but no treatment is provided.

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Emam Hossein clinic

Full name of responsible person

Behzad Ghadiri

Street address

Emam Hossein clinic, Pasdaran street, Birjand

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Birjand University of Medical Sciences

Full name of responsible person

Dr. Mohammadreza Miri

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Research and Technology Deputy of Birjand
University of Medical Sciences, Ghafari Street,

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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

Birjand 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**

Birjand University of Medical Sciences

Full name of responsible person

Behzad Ghadiri

Position

student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

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No. 88, Saeedi 12 Ave, West Saeedi street, Modares
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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Birjand University of Medical Sciences

Full name of responsible person

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Position

student

Latest degree

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Person responsible for updating data

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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 need.

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

Not applicable