

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

Effect of low level laser therapy on pain control in initial stage of fixed orthodontic treatment

Protocol summary

Study aim

Effect of low level laser therapy on pain control in initial stage of fixed orthodontic treatment

Design

Thirty-six patients were enrolled in this randomized, single-blind clinical trial. Using random allocation software, one quadrant in the patient's lower jaw was considered as the intervention group and the other quadrant in the same patient as the placebo group.

Settings and conduct

This single-blind study (patients) was performed orally in the orthodontics department of the School of Dentistry, Qazvin University of Medical Sciences, Iran. For patients with a pre-determined letter A, a laser is used in the right mandibular quadrant and the left mandibular quadrant is exposed to red light (placebo). In patients for whom the letter B was predetermined, the left quadrant of the mandible was irradiated and the right quadrant was irradiated with red light (placebo).

Participants/Inclusion and exclusion criteria

Admission: Patient with permanent dental system (premolars and permanent first and second molars have erupted); no history of taking analgesics in a recent week; No systemic disease or chronic pain in the mouth and teeth; Moderate and severe crowding based on Little's irregularity index in mandible (4-9 mm) No entry: taking painkillers after the initial archwire and laser radiation

Intervention groups

One quadrant in the patient's mandible was considered as the intervention group and the other quadrant as the placebo group. Laser irradiation was performed 5 minutes before the initial wiring and immediately after the initial wiring. On the intervention side, the laser was irradiated on the buccal and palatal surfaces for 15 seconds.

Main outcome variables

Pain during chewing after placing the initial wire for up to 7 days at the end of every 24 hours; Spontaneous pain

after placing the initial wire for up to 7 days at the end of every 24 hours

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210404050846N1**

Registration date: **2021-12-21, 1400/09/30**

Registration timing: **retrospective**

Last update: **2021-12-21, 1400/09/30**

Update count: **0**

Registration date

2021-12-21, 1400/09/30

Registrant information

Name

Rojin Khanmohammad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6640 3269

Email address

rojin.khanmohammad@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-08-16, 1399/05/26

Expected recruitment end date

2021-06-20, 1400/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of low level laser therapy on pain control in initial stage of fixed orthodontic treatment

Public title

Effect of low level laser therapy on pain control in initial stage of fixed orthodontic treatment

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Patient with permanent dentition Patient without a history of taking painkillers in the last week Patient with moderate and severe crowding based on Little's irregularity index in mandible (4-9 mm)

Exclusion criteria:

Taking painkillers after the initial archwire and laser radiation

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **42**

More than 1 sample in each individual

Number of samples in each individual: **2**

One side of the mandible is considered as the intervention group and the other side is considered as the control group

Randomization (investigator's opinion)

Randomized

Randomization description

By allocation software random, one quadrant in the patient's mouth is randomly considered as the intervention group and the other quadrant as the placebo group

Blinding (investigator's opinion)

Single blinded

Blinding description

The study participant did not know which side of the jaw was exposed to the laser

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Qazvin University of Medical Sciences

Street address

Qazvin University of Medical Sciences, Shahid Bahonar Blv

City

Qazvin

Province

Qazvin

Postal code

3415759811

Approval date

2020-08-15, 1399/05/25

Ethics committee reference number

IR.QUMS.REC.1399.173

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

Evaluation of low-intensity laser effect on orthodontic pain reduction after placement of first archwire

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Reduction of spontaneous pain and pain during chewing after placing the initial wire

Timepoint

Immediately after placing the initial wire and up to 1 week at the end of every 24 hours

Method of measurement

visual analogue scale

Secondary outcomes

empty

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

Intervention group: Right or left mandibular quadrant exposed to low intensity 940 nm laser with 100 mw power

Category

Treatment - Devices

2**Description**

Control group: The right or left quadrant of the mandible,

which is exposed only to low-intensity 940 nm laser red light

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Qazvin University of Medical Sciences

Full name of responsible person

Parviz Padisar

Street address

Qazvin University of Medical Sciences, Shahid
Bahonar Blv

City

Qazvin

Province

Qazvin

Postal code

3415759811

Phone

+98 28 3335 3061

Email

dentistry@qums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Parviz Padisar

Street address

Qazvin University of Medical Sciences, Shahid
Bahonar Blv

City

Qazvin

Province

Qazvin

Postal code

3415759811

Phone

+98 28 3335 3061

Email

dentistry@qums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Qazvin 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

Qazvin University of Medical Sciences

Full name of responsible person

Parviz Padisar

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Orthodontics

Street address

Qazvin University of Medical Sciences, Shahid
Bahonar Blv

City

Qazvin

Province

Qazvin

Postal code

3415759811

Phone

+98 28 3335 3061

Email

drppadisar@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Parviz Padisar

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Orthodontics

Street address

Qazvin University of Medical Sciences, Shahid
Bahonar Blv

City

Qazvin

Province

Qazvin

Postal code

3415759811

Phone

+98 28 3335 3061

Email

drppadisar@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Parviz Padisar

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Orthodontics

Street address

Qazvin University of Medical Sciences, Shahid
Bahonar Blv

City

Qazvin

Province

Qazvin

Postal code

3415759811

Phone

+98 28 3335 3061

Email

drppadisar@gmail.com

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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data is potentially shareable after unidentified
individuals

When the data will become available and for how long

Access period starts 6 months after the results are
published

To whom data/document is available

The data will be available to researchers working in
academia and in industry

Under which criteria data/document could be used

All scientific analyzes to advance science and technology
are allowed on the data of this study.

From where data/document is obtainable

For any information, you can refer to this email address:
ppadisar@gmail.com

What processes are involved for a request to access data/document

To receive the documents, you can send your personal
details and request to this email address:
ppadisar@gmail.com

Comments