

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Aug 2026

A clinical trial to compare the effectiveness of ibuprofen with low-level laser on acupuncture points in pain reduction after initial archwire placement in orthodontic patient

Protocol summary

Study aim

To compare the effectiveness of ibuprofen with low-level laser on acupuncture points in pain reduction after initial archwire placement in orthodontic patient

Design

Totally, 80 patients whose undergoing orthodontic treatment and referring to Dental Clinic of Mashhad Faculty of Dentistry, Mashhad, Iran. In this single-blind, controlled clinical trial, the patients are assigned into parallel groups using simple sampling methods.

Settings and conduct

Patients whose undergoing orthodontic treatment and referring to Dental Clinic of Mashhad Faculty of Dentistry, are chosen as the participants of the study. In this single-blind study, sealed opaque envelopes will be used to conceal the sequencing. The person responsible for data collection is blind to group allocation and the type of intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Female with aged range 14-30 years; no history of systemic disease; nonuse of analgesic. Exclusion criteria: Having drug intolerance; having gastrointestinal disorders; pregnant and lactating women; having special medical condition.

Intervention groups

Intervention group I will receive 810 nm wavelength laser with 200 mW power for 30 seconds around the 6 points area around the root of tooth after initial archwire placement. Intervention group II will receive 810 nm wavelength laser with 200 mW power for 60 seconds in 5 acupuncture points after initial archwire placement. Intervention group III will receive 400 mg ibuprofen every 8 hours after initial archwire placement. Control group will receive laser off in acupuncture points after initial archwire placement.

Main outcome variables

Evaluation and comparison of the pain rate in chewing,

biting, tipping anterior teeth, and put posterior teeth on each other in 2 and 6 hours, as well as 2, 3, 5 and 7 days after the intervention in the three intervention and control groups.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200622047886N1**

Registration date: **2020-06-29, 1399/04/09**

Registration timing: **prospective**

Last update: **2020-06-29, 1399/04/09**

Update count: **0**

Registration date

2020-06-29, 1399/04/09

Registrant information

Name

Melika Hagpanahi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3883 2300

Email address

ahrarif1@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-22, 1399/05/01

Expected recruitment end date

2021-07-23, 1400/05/01

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
A clinical trial to compare the effectiveness of ibuprofen with low-level laser on acupuncture points in pain reduction after initial archwire placement in orthodontic patient

Public title
The effectiveness of low-level laser on acupuncture points in pain reduction in orthodontic patient

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Female with aged range 14-30 years No history of systemic disease Nonuse of analgesic
Exclusion criteria:
 Having drug intolerance Having gastrointestinal disorders Pregnant and lactating women Having special medical condition

Age
From **14 years** old to **30 years** old

Gender
Female

Phase
1

Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
The subjects will be randomly assigned into three groups of 20 patients with blocks of 2, 4, 6 and 8 using randomization method. A noninvolved researcher will determine the random assignment sequencing in sampling using a statistical analysis system (SAS), computer software. Accordingly, the participants were given codes and assigned into the three intervention and control groups.

Blinding (investigator's opinion)
Single blinded

Blinding description
Patients whose undergoing orthodontic treatment and referring to Dental Clinic of Mashhad Faculty of Dentistry, are chosen as the participants of the study. In this single-blind study, sealed opaque envelopes will be used to conceal the sequencing. The person responsible for data collection is blind to group allocation and the type of intervention.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mashhad University of Medical Sciences

Street address

Vice Chancellor for Research, Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah Street

City

Mashhad

Province

Razavi Khorasan

Postal code

9195965919

Approval date

2019-11-13, 1398/08/22

Ethics committee reference number

IR.MUMS.DENTISTRY.REC.1398.103

Health conditions studied

1

Description of health condition studied

Orthodontic

ICD-10 code

Z46.4

ICD-10 code description

Fitting and adjustment of orthodontic device

Primary outcomes

1

Description

The pain rate in chewing

Timepoint

2 and 6 hours, as well as 2, 3, 5 and 7 days after the intervention

Method of measurement

Visual Analogue Scale (VAS)

2

Description

The pain rate in biting

Timepoint

2 and 6 hours, as well as 2, 3, 5 and 7 days after the intervention

Method of measurement

Visual Analogue Scale (VAS)

3

Description

The pain rate when tipping anterior teeth

Timepoint

2 and 6 hours, as well as 2, 3, 5 and 7 days after the intervention

Method of measurement

Visual Analogue Scale (VAS)

4

Description

The pain rate when put posterior teeth on each other

Timepoint

2 and 6 hours, as well as 2, 3, 5 and 7 days after the intervention

Method of measurement

Visual Analogue Scale (VAS)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group I will receive 810 nm wavelength laser with 200 mW power for 30 seconds around the 6 points area around the root of tooth after initial archwire placement.

Category

Treatment - Other

2

Description

Intervention group: Intervention group II will receive 810 nm wavelength laser with 200 mW power for 60 seconds in 5 acupuncture points after initial archwire placement.

Category

Treatment - Other

3

Description

Intervention group: Intervention group III will receive 400 mg ibuprofen every 8 hours after initial archwire placement.

Category

Treatment - Drugs

4

Description

Control group: Control group will receive laser off in acupuncture points after initial archwire placement.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Mashhad Faculty of Dentistry Dental Clinic

Full name of responsible person

Melika Hagpanahi

Street address

Dental Clinic of Mashhad Faculty of Dentistry,
Opposite Mellat Park, Vakilabad Blvd

City

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Province

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Postal code

9177948959

Phone

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Email

melikah750@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

Street address

Vice Chancellor for Research, Mashhad University of
Medical Sciences, Ghoreishi building, Daneshgah
Street

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+98 51 3841 1538

Email

vcresearch@mums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad 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**

Mashhad University of Medical Sciences

Full name of responsible person

Melika Hagpanahi

Position

Student

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Latest degree

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

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Full name of responsible person

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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

Not applicable

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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The total data to be included are the primary and
secondary effects to be shared.

When the data will become available and for how long

6 months after printing results

To whom data/document is available

Our data will only be available to researchers working in
science center and university.

Under which criteria data/document could be used

Our data will be available for scholars working in science
center and university.

From where data/document is obtainable

Melika Hagpanahi provides the analysis code to the
applicants via email: melikah750@gmail.com

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

Applicants can respond to the email of the respondent
and receive a response within a week.

Comments