Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Jun 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
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Razavi Khorasan
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9177948959
Phone
+98 51 3883 2300
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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Province
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Postal code
9138813944
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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
Street address
Dental Clinic of Mashhad Faculty of Dentistry, Opposite Mellat Park, Vakilabad Blvd
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Person responsible for updating data

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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