

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

Comparison of the effect of low-level laser therapy and acetaminophen on pain after the separator placement in orthodontic treatment

Protocol summary

Summary

Orthodontic movement associated pain is one of the problems in the early days after the force application. Laser irradiation is one of the latest topical techniques and effective on pain relief. The aim of this study is comparison of low level laser effect with acetaminophen on pain relief after separator placement of orthodontic treatment. This randomized, double-blind clinical trial will be done in 1392. For 66 samples (33 men and 33 women) aged 18 to 30 years of orthodontic patients or volunteer students, eight separators will be placed in the mesial and distal of the first molars teeth. Participants will be randomly matched with one of the three groups, sex matching also will be made: the laser group (laser radiation - drug placebo), acetaminophen group (laser off - drug) and laser-acetaminophen group (laser radiation - drug). The participants will receive 9 tablets (acetaminophen 500 mg Jalinous Company or similar placebo) that will take an hour before separator placement and will continue every 6 hours. Laser will radiate immediately and 24 hours after separator placement to eight points per quadrant for 4 seconds that will be low level laser or off with the same sound. Participants will be specified the pain that they feel at 0, 1, 6, 12, 24, 48 hours after separator placement by numerical scale of zero (no pain) to 10 (worst pain) in the questionnaire. Separators will be removed 48 hours after placement.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013022312568N1**

Registration date: **2013-03-27, 1392/01/07**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2013-03-27, 1392/01/07

Registrant information

Name

Fariba Shahri

Name of organization / entity

Zahedan University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 54 1242 0940

Email address

shahri@zaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Research and Technology Assistance of Zahedan University of Medical Science

Expected recruitment start date

2013-04-04, 1392/01/15

Expected recruitment end date

2013-06-05, 1392/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of low-level laser therapy and acetaminophen on pain after the separator placement in orthodontic treatment

Public title

Laser effects on pain after separator placement in orthodontic treatment.

Purpose

Supportive

Inclusion/Exclusion criteria
 Intrusion criteria: Age 18 to 30 years; All teeth in two jaws till second molar before treatment, are fully grown and second premolars, first and second molars are in contact; So let's put the two separator at the mesial and distal to the four first molars. Exclusion criteria: Dependence on psychoactive drugs; History of taking anti epileptic and antidepressant drugs; A history of chronic systemic diseases such as liver disease, lung, kidney and heart disease and so on; History of neuropathic disorders (diabetic neuropathy, trigeminal neuralgia (trigeminal) and glossopharyngeal neuralgia etc; Active oral herpes infection (simplex and zoster); History of temporomandibular arthritis; Infectious diseases, autoimmune diseases, immune deficiencies, HIV; History of allergic diseases, and organ transplantation; Diabetes and metabolic diseases; Pregnancy; Sensitivity to acetaminophen; Signs of infection or periodontal disease; History of mental and previous neurological or psychiatric problems; History of previous pain or chronic pain; History of analgesic drugs consumption; Addiction to drugs or alcohol; Unbearable pain (NRS above 7) and medication help; Early exit of separators from the space between the teeth; The history of tooth extraction from 2 weeks ago.

Age
 From **18 years** old to **30 years** old

Gender
 Both

Phase
 N/A

Groups that have been masked
No information

Sample size
 Target sample size: **66**

Randomization (investigator's opinion)
 Randomized

Randomization description

Blinding (investigator's opinion)
 Double blinded

Blinding description

Placebo
 Used

Assignment
 Parallel

Other design features

Secondary Ids
 empty

Ethics committees

1

Ethics committee

Name of ethics committee
 Research and Technology Assistance of Zahedan University of Medical Science

Street address
 Zahedan University of Medical Science, Dr. Hesabi

square, Zahedan

City
 Zahedan

Postal code

Approval date
 2013-03-12, 1391/12/22

Ethics committee reference number
 91-2064

Health conditions studied

1

Description of health condition studied
 Orthodontic pain

ICD-10 code
 R52.0

ICD-10 code description
 Acute pain

Primary outcomes

1

Description
 pain

Timepoint
 0, 1, 6, 12, 24, 48 hours after separator placement

Method of measurement
 By individual participants is determined by the numeric rating scale (NRS). 0 = no pain to 10 = worst pain imaginable

Secondary outcomes
 empty

Intervention groups

1

Description
 Group 1: Under laser irradiation, and the use of placebo drug

Category
 Placebo

2

Description
 Group 2: the laser off and the use of Acetaminophen

Category
 Treatment - Drugs

3

Description
 Group 3: Under laser irradiation, and the use of Acetaminophen

Category
 Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Specialized clinic of Zahedan Dental University

Full name of responsible person

Dr. Fariba Shahri

Street address

Zahedan Dental College, Mehr street, Zahedan

City

Zahedan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research and Technology Assistance of Zahedan
University of Medical Science

Full name of responsible person

Dr. Hamid Reza Mahmood Zade Sagheb

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Zahedan University of Medical Science, Dr Hesabi
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Zahedan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Research and Technology Assistance of Zahedan
University of Medical Science

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Zahedan University of Medical Science

Full name of responsible person

Adel Sharifi Rayeni

Position

Dentistry student

Other areas of specialty/work

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Doctor Fariba Shahri

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Person responsible for updating data

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Dental student

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty
Informed Consent Form
empty
Clinical Study Report
empty

Analytic Code
empty
Data Dictionary
empty