

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The Comparison of Efficacy of Pharmacological (Ibuprofen) with Non-Pharmacological (Photobiomodulation and Chewing Gum) Interventions on Reducing Pain in Teeth with Elastomeric Separators

Protocol summary

Study aim

Determination Of The Effect Of Drug Interventions (Ibuprofen) With Non-Pharmacological (Photomodulation And Chewing Gum) On Pain Associated With Elastomeric Separator

Design

Clinical trial, with parallel groups, single-blind, randomized, phase 3 on 90 patients. The RANDBETWEEN function of Excel software was used for randomization.

Settings and conduct

In this randomized clinical trial study, about 90 patients requiring an elastomeric spacer on the right side of the mandible were included in the study. Ibuprofen, laser, and chewing gum were used to reduce pain. Patients are given a McGill Pain Questionnaire to report their pain. This study is designed to be one-sided blind. Due to the nature of the interventions, it is not possible to blind the patient, but the outcome assessor has no Information of the study hypothesis and how the study groups are assigned.

Participants/Inclusion and exclusion criteria

Patients Need Elastomeric Separators Dental Tight Contact No Systemic Disease And Use Of Painkillers

Intervention groups

Ibuprofen, chewing gum, PBMT groups

Main outcome variables

The main outcome of this study is pain, which is measured by using the McGill Pain Questionnaire.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210927052611N1**

Registration date: **2022-03-14, 1400/12/23**

Registration timing: **registered_while_recruiting**

Last update: **2022-03-14, 1400/12/23**

Update count: **0**

Registration date

2022-03-14, 1400/12/23

Registrant information

Name

Maryam Malekpour salimezadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 83 3823 1196

Email address

m_malekpour83@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-03-09, 1400/12/18

Expected recruitment end date

2022-04-19, 1401/01/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Comparison of Efficacy of Pharmacological (Ibuprofen) with Non-Pharmacological (Photobiomodulation and Chewing Gum) Interventions on Reducing Pain in Teeth with Elastomeric Separators

Public title

The Comparison of Ibuprofen, Chewing Gum and laser in orthodontic pain relief

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Male and female patients between 30 and 15 years old seeking fixed orthodontic treatment No pain in the mouth (teeth and gums) when starting the study The first molar teeth are fully erupted Presence of the first molar teeth in the opposite arch interproximal tight contact between teeth adjacent to the first molar irregularity index more than 2 mm No previous tooth restoration, root canal treatment and periodontal disease in the examined tooth

Exclusion criteria:

Failure to complete or incomplete form of informed consent or VAS questionnaire Take painkillers and other painkillers the day before the separators are placed smoking Pregnancy and Breastfeeding PBM usage history Detachment of one or more elastomeric separators Lack of second premolars or second molars in the arch Participants with a pain threshold higher (greater than 1500 g) or lower (less than 500 g)

Age

From **15 years** old to **30 years** old

Gender

Both

Phase

3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

A Table of Random Numbers is Used For Randomization. In Excel Software Environment, Four-Digit Codes Are Generated Using The RANDBETWEEN Command. Each Patient Is Assigned A 4-Digit Code. If The Far Right Digit Is 1, 2, And 3, The Patient Is In The Photobiomodulation Group, Numbers 4, 5, And 6 Is Assigned In The Chewing Gum Group And Eventually Numbers 7, 8, And 9 Is Assigned In The Ibuprofen Group. Zero Does Not Count In Encodings. All Codes Are Are Written On Paper And Stored In Specific Envelopes. The Envelopes Are Arranged Randomly And The Responsible Secretary, Who Is Aware Of The Objectives Of The Study, Will Give Them One Of These Envelopes Before Entering The Doctor's Room When Reviewing The Inclusion Criteria And Recording Patient Information. The Secretary Is Not Aware Of The Study Hypothesis And Is Not Aware Of The Details Of The Codes For Assigning To Groups. The Doctor Will Decide On The Treatment Process For The Patient Based On The Specified Code.

Blinding (investigator's opinion)

Single blinded

Blinding description

This Study Is Designed To Be One-Sided Blind. Due To The Nature Of The Interventions, It Is Not Possible To

Blind The Patient, But The Outcome Assessor Has No Knowledge Of The Study Hypothesis And How The Study Groups Are Assigned.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kermanshah University of Medical Sciences

Street address

Floor 2, No. 62, Bargh 3 St., Bistodoebahman, Kermanshah, Iran

City

Kermanshah

Province

Kermanshah

Postal code

6714636577

Approval date

2022-03-08, 1400/12/17

Ethics committee reference number

IR.KUMS.REC.1400.841

Health conditions studied

1

Description of health condition studied

درد ناشی از سپریتور الاستومریک ارتودنسی

ICD-10 code

ICD-10 code description

2

Description of health condition studied

Pain due to elastomeric orthodontic separators

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The main outcome of this study is pain, which is measured using the McGill Pain Questionnaire.

Timepoint

At the beginning of the study (before the intervention) and immediately, 2, 12 and 24 hours and 2, 5 and 7 days, after the intervention

Method of measurement

McGill Pain Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: photobiomodulation, chewing gum, ibuprofen

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center**Name of recruitment center**

Mehremadar dental clinic

Full name of responsible person

Bahram Azizi

Street address

3rd, Corner 3rd Bargh st. (Near Rojano Fast Food),
Bargh Ave., 22 Bahman, Kermanshah

City

Kermanshah

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Kerman

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6714636577

Phone

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Email

m_malekpour83@yahoo.com

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Kermanshah University of Medical Sciences

Full name of responsible person

Zohreh Rahimi

Street address

School of Medicine, Kermanshah University of Medical
Sciences, Kermanshah, Iran

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Phone

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Email

zrahimi@kums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Kermanshah 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**

Kermanshah University of Medical Sciences

Full name of responsible person

Maryam Malekpour salimezadeh

Position

Dentistry student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

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

Kermanshah University of Medical Sciences

Full name of responsible person

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Position

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Person responsible for updating data

Contact

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Position
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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

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

The pain questionnaire and the anxiety measurement questionnaire can be shared.

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

orthodontists

Under which criteria data/document could be used

Use in future research

From where data/document is obtainable

Send email to the person in charge of research

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

Sending a scientific resume and documentation via email to the researcher

Comments