

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

A comparison between efficacy of ketoprofen and benzocaine patches on post orthodontic pain

Protocol summary

Summary

The aim of the present study is to compare the effect of ketoprofen and benzocaine patches in reduction of pain after separator placement. This study will be conducted as a double-blind controlled randomized clinical trial. 24 cases will be selected from patients referred to orthodontic department of dental school of Shahid Beheshti university of medical sciences and two private offices for fix orthodontic treatment. To eliminate individual differences in the experience of pain research will be conducted as a split mouth trial. After separator placement, patients will take benzocaine and ketoprofen patches and all subjects will be instructed to use the patches ever 6 hours until 3 days after separator placement. Patches were randomly placed in right and left sides of the jaw. Patients will record their pain perception at times of 2 h, 6h, 24h, day2(6 pm), day3(10am and 6 pm) and day7(10 am and 6 pm) using 100 scores visual analogue scale. Eventually pain perception of patients will be assessed with respect of type of the applied patches and statistical analyses.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014020316466N1**

Registration date: **2014-04-17, 1393/01/28**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-04-17, 1393/01/28

Registrant information

Name

Ladan Eslamian

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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ladan.eslamian@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Dentofacial Deformities Research Center of shahid beheshti university of medical sciences

Expected recruitment start date

2014-02-24, 1392/12/05

Expected recruitment end date

2014-05-26, 1393/03/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparison between efficacy of ketoprofen and benzocaine patches on post orthodontic pain

Public title

Prevention of orthodontic pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: participants, in good general health without any reported systematic diseases; no concurrent use of analgesics and anti-inflammatory drugs; requiring banding of posterior teeth and placement of two or more elastomeric separators as a part of orthodontic treatment; caries-free dentition with healthy periodontium and without any endodontic problems in

the posterior part of the mouth; presence of antagonist teeth in the opposite arch and absence of posterior open bite and interdental spaces. Patients were excluded from the study if they used analgesics and anti-inflammatory drugs during the study, did not complete the questionnaire, did not use or improperly used benzocaine or ketoprofen patches, or removed elastomeric separators.

Age

From **11 years** old to **35 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **24**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

shahid beheshti university of medical science-dental university

Street address

Chamran Exp.way,Daneshjoo blvd

City

tehran

Postal code

19834

Approval date

2012-04-21, 1391/02/02

Ethics committee reference number

471

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

Orthodontic pain

ICD-10 code

XXI

ICD-10 code description

Factors influencing health status and contact with health services

Primary outcomes**1****Description**

pain

Timepoint

2 h, 6h, 24h, day2(6 pm), day3(10am and 6 pm) and day7(10 am and 6 pm)

Method of measurement

100 scores visual analogue scale

Secondary outcomes**1****Description**

production

Timepoint

2 h, 6h, 24h, day2(6 pm), day3(10am and 6 pm) and day7(10 am and 6 pm)

Method of measurement

visual analogue scale

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

benzocaine patch, each 6 hours 1 patch until 3 days The patches contained: Benzocaine(C₉H₁₁NO₂), propylene glycol, di chloro methan, aspartam, poly vinyl prolidine, ethanol and hydroxy propyl methyl cellulose. Solvent casting was performed to make patches. At first the materials are weighted and solve in one proper solvent, then are mixed by magnetic mixer (Heidolph stirrer, model:MR3001K, Germany) for 30 minutes. If no sediment observed, and the solution is clear, each 50 cc will be placed in the same sized plates for 48 hours under the hood for evaporation. To prevent contamination, a funnel should be placed above the plates; with reducing the speed of dissolving, the contents of the films would not migrate and the final homogeneity of the film will be maintained. Hydroxy propyl methyl cellulose and polyvinyl prolidin will provide proper viscosity for the film to adhere to oral mucosa. Propyl glycol is used for lavigation of Benzocaine or Ketoprofrn. Dichloro methan and ethanol solvents will be used to dissolve the polymers after lavigation. To sweeten the films and making their taste more acceptable, Aspartam will be added. When the apperance of the provided material (film) is acceptable, they are cut into 0.5 x 1.5 cm pieces and hold in periapical radiographic film covers. In each section 2 films are placed. For each patient 12 Benzocaine and 12 ketoprofen patches are needed and the patients have to use them for 3 days. After placement of elastic

separators in proximal of right and left 1st molars, the patients will be instructed to use the keto and benzo patches on both sides of the arch simultaneously to perform a split-mouth study. Since pain is subjective, split-mouth study reduces the individual differences. Pilot study was performed to make certain that the two patches do not mix to reduce the study value. The patients and the operator would not know which patch contain which element and the patches will be divided to A and B to make the study a double blind one and the patches will be randomly assigned to right and left sides by coin method. The amount of pain will be assessed by VAS scores(0 to 100) and the patients will fill the questioners at the determined times : 2,6 ,12 and 24hours, day 2 and day 3(at 10 am and 6 pm) after separator placement. The amount of pain in scores will be calculated for the two patches and the difference reported.

Category

Treatment - Drugs

2

Description

ketoprpfen patch, each 6 hours 1 patch until 3 days The patches contained: Ketoprufen(C16H14O3), propylen glycol, di chloro methan, aspartam, poly vynil prolidine, ethanol and hydroxy propyl methyl cellulose. Solvent casting was performed to make patches. At first the materials are weighted and solve in one proper solvent, then are mixed by magnetic mixer (Heidolph stirrer, model: MR3001K, Germany) for 30 minutes. If no sediment observed, and the solution is clear, each 50 cc will be placed in the same sized plates for 48 hours under the hood for evaporation. To prevent contamination, a funnel should be placed above the plates; with reducing the speed of dissolving, the contents of the films would not migrate and the final homogeneity of the film will be maintained. Hydroxy propyl methyl cellulose and polyvinyl prolidin will provide proper viscosity for the film to adhere to oral mucosa. Propyl glycol is used for lavigation of Benzocaine or Ketoprufrn. Dichloro methan and ethanol solvents will be used to dissolve the polymers after lavigation. To sweeten the films and making their taste more acceptable, Aspartam will be added. When the apperance of the provided material (film) is acceptable, they are cut into 0.5 x 1.5 cm pieces and hold in periapical radiographic film covers. In each section 2 films are placed. For each patient 12 Benzocaine and 12 ketoprufen patches are needed and the patients have to use them for 3 days. After placement of elastic separators in proximal of right and left 1st molars, the patients will be instructed to use the keto and benzo patches on both sides of the arch simultaneously to perform a split-mouth study. Since pain is subjective, split-mouth study reduces the individual differences. Pilot study was performed to make certain that the two patches do not mix to reduce the study value. The patients and the operator would not know which patch contain which element and the patches will be divided to A and B to make the study a double blind one and the patches will be randomly assigned to right and left sides

by coin method. The amount of pain will be assessed by VAS scores(0 to 100) and the patients will fill the questioners at the determined times : 2,6 ,12 and 24hours, day 2 and day 3(at 10 am and 6 pm) after separator placement. The amount of pain in scores will be calculated for the two patches and the difference reported.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr. Eslamian orthodontic office

Full name of responsible person

Dr. Ladan Eslamian

Street address

#60, Satari bvd, Africa Blvd

City

Tehran

2

Recruitment center

Name of recruitment center

Orthodontic Department of Shahid Beheshti

Univercity of Medical Science

Full name of responsible person

Dr. Ladan Eslamian- Mrs Foomani

Street address

Chamran exp.way. Daneshjoo blvd.

City

Tehran

3

Recruitment center

Name of recruitment center

Dr. Naseh dental office

Full name of responsible person

Dr. Roya Naseh

Street address

City

Qazvin

4

Recruitment center

Name of recruitment center

Dr. Haqiqat Naseri dental office

Full name of responsible person

Dr. Sara Haqiqat Naseri

Street address

City

Qazvin

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Dentofacial Deformities Research Center of Shahid Beheshti University of Medical Science

Full name of responsible person

Dr.asghar Ebadifar

Street address

Shahid Beheshti Dental School

City

Tehran

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

Yes

Title of funding source

Dentofacial Deformities Research Center of Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences-Private office

Full name of responsible person

Hamide Motaharifard- Dr. Naseh

Position

Dental student-Orthodontist

Other areas of specialty/work**Street address**

Chamran Exp.way,Daneshjoo blvd-dehkhod street

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

Shahi Beheshti University of Medical Sciences, Dental

& pharmacology schools

Full name of responsible person

Ladan Eslamian- Seyed Alireza Mortazavi

Position

Professor of Orthodontics-Professor of Pharmaceutics PhD

Other areas of specialty/work**Street address**

Chamran Exp.way, Daneshjoo blvd-Chamran Exp.way, Across Vali-asr Ave.

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Person responsible for updating data

Contact**Name of organization / entity**

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Full name of responsible person

Ali Borzooabadi Farahani-Arash Farzan

Position

DDS, MScD (Cardiff), MOrth RCS (Ed)-Postgraduate student of orthodontics

Other areas of specialty/work**Street address**

Warwick Dentistry, Warwick Medical School, University of Warwick, Coventry, CV4 7AL, UK - Chamran Exp.way-Daneshjoo blvd

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Province

London-Tehran

Postal code**Phone**

00447803514186-00982129902304

Fax**Email**

faraortho@yahoo.com; dr.arash.farzan@gmail.com

Web page address

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