

# 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

+98 21 2240 3010

##### Email address

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(C<sub>9</sub>H<sub>11</sub>NO<sub>2</sub>), 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 24 hours, 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**

ketoprfen patch, each 6 hours 1 patch until 3 days. The patches contained: Ketoprufen (C<sub>16</sub>H<sub>14</sub>O<sub>3</sub>), propylen 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 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 24 hours, 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**

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**Postal code**

19834

**Phone**

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**Fax****Email**

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**Web page address**

### 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**

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**Web page address**

### Person responsible for updating data

**Contact****Name of organization / entity**

Orthodontics, Warwick Dentistry, Warwick Medical School, University of Warwick, Coventry, CV4 7AL, U

**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

**City**

London-Tehran

**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*