

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparative effect of Ketoprofen and Benzocaine chewing gums in reducing orthodontic pain

#### Protocol summary

##### Summary

Background: Pain relief is important during orthodontic treatment. The aim of this study is to compare the effect of Ketoprofen and Benzocaine gums in pain reduction during fixed orthodontic treatment. Methods: 30 patients with age range of 15-25 years old who had pain in previous sessions, will randomly be divided into 3 groups, each receives one type of experimental gums including ketoprofen, Benzocaine and placebo chewing gums. After giving instructions to the patients, they will receive all types of gums frequently, considering the wash out period. They will use the chewing gums immediately after each orthodontic performance and continue them at every 8 hours interval. Patients will record their pain perception at times of 2, 6, 24 hours, and 2, 3 and 7 days using 100 scores visual analogue scale. Friedmann and Wilcoxon analysis are used to compare the mean of pain scores among 3 groups to determine which chewing gum in which stage causes the pain relief.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014041416466N3**

Registration date: **2014-06-27, 1393/04/06**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2014-06-27, 1393/04/06

##### 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

Shahid Beheshti University of Medical Sciences

###### Expected recruitment start date

2013-09-23, 1392/07/01

###### Expected recruitment end date

2014-02-20, 1392/12/01

###### Actual recruitment start date

empty

###### Actual recruitment end date

empty

###### Trial completion date

empty

###### Scientific title

Comparative effect of Ketoprofen and Benzocaine chewing gums in reducing orthodontic pain

###### Public title

Management of orthodontic pain

###### Purpose

Prevention

###### Inclusion/Exclusion criteria

Inclusion criteria: participants, in good general health without any reported systematic diseases; no concurrent use of analgesics and anti-inflammatory drugs; feel pain more than 50 according to VAS after previous appointment; caries-free dentition with healthy periodontium and without any endodontic problems in the posterior part of the mouth; crowding between 6-8mm and stage of TX in levelling and alignment stage. Patients will be 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 chewing gums.

### Age

From **15 years** old to **25 years** old

### Gender

Both

### Phase

N/A

### Groups that have been masked

*No information*

### Sample size

Target sample size: **30**

### Randomization (investigator's opinion)

Randomized

### Randomization description

### Blinding (investigator's opinion)

Double blinded

### Blinding description

### Placebo

Used

### Assignment

Crossover

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Shahid Beheshti University of Medical Sciences

##### Street address

Shahid Beheshti University of Medical Sciences,  
Daneshjoo blvd, Chamran Exp.way

##### City

Tehran

##### Postal code

19834

#### Approval date

2014-01-05, 1392/10/15

#### Ethics committee reference number

660

## 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(10am and 6 pm), day3(10am and 6 pm) and day7(10 am and 6 pm)

#### Method of measurement

100 scores visual analogue scale

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

ketoprofen(Keto) chewing gum was manufactured with 75mg ketoprofen in R& D department of Minoo industrial company under the consultant pharmacologist. The chewing gum consists of gumbase,sorbitol,Xylitol,malnitro,aspartam,A3sulfamK,ocaliptus essence.Ketoprofen was provided from Switzerland.Keto gum will be instructed immediately after each orthodontic intervention(considering wash-out time) for each of the 30 patients and will be continued every 8 hours till day 7.

#### Category

Treatment - Drugs

### 2

#### Description

Benzocain chewing gum (Benzo) chewing gum was manufactured with 20% benzocain in R& D department of Minoo industry company under the consultant pharmacologist. The chewing gum consists ofgumbase,sorbitol,Xylitol,malnitro,aspartam,A3sulfamK,ocaliptus essence.Benzo was provided from Switzerland.Benzo gum will be instructed immediately after each orthodontic intervention for each of the 30 patients ( providing wash-out time) and will be continued every 8 hours till day 7.

#### Category

Treatment - Drugs

### 3

#### Description

Placebo chewing gum chewing gum was manufactured in R& D department of Minoo industry company under the consultant pharmacologist. The chewing gum consists ofgumbase,sorbitol,Xylitol,malnitro,aspartam,A3sulfamK,ocaliptus essence .Placeboo gum will be used immediately after each orthodontic intervention for each of the 30 patients(considering wash-out time) and will be continued every 8 hours till day 7.

#### Category

Placebo

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Orthodontic Department of Shahid Beheshti  
University of Medical Science

**Full name of responsible person**

Sara Yousefinia

**Street address**

Chamran exp.way. Daneshjoo blvd.

**City**

Tehran

2

### Recruitment center

**Name of recruitment center**

Dr. Eslamian orthodontic office

**Full name of responsible person**

Dr. Ladan Eslamian

**Street address**

#60, Satari Blvd, Africa Blvd

**City**

Tehran

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Dr. Maryam Moezizadeh

**Street address**

Shahid Beheshti University of Medical Sciences, 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**

Shahid Beheshti University of Medical Sciences

**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

**Full name of responsible person**

Sara Yousefinia

**Position**

Postgraduate student of orthodontic department

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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

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yousefiniasara@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*