

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 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)

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+98 21 2240 3010

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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 bvd, 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

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School

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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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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