

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

Evaluation of the effect of benzocaine-contained tooth paste on relieving orthodontic pain

Protocol summary

Summary

The aim of the present study is to assess effectiveness of benzocaine-contained toothpaste in decreasing pain caused by fixed orthodontics. Study population consists of all patients undergoing orthodontic treatment and experience pain after appointment. By considering 20% lost to follow up, sample size was calculated to be 33. Inclusion criteria include, fixed orthodontic patients in initial appointments who report pain experience after previous appointment. Presence of liver and kidney problems and also allergy to local anesthesia lead to exclusion of samples. The study is designed to be cross-over, i.e patients would receive benzocaine toothpaste, placebo toothpaste or only questionnaire in three sequential appointments. Patients were instructed to use toothpaste for 3 days and mark their pain in a zero to 100 scale in predetermined intervals. Primary outcome is pain reported by patient. Between each appointment there is 4 weeks interval.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015010120523N1**

Registration date: **2015-04-16, 1394/01/27**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-04-16, 1394/01/27

Registrant information

Name

Sepideh Soheilifar

Name of organization / entity

Hamedan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Dental research center, Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2015-03-20, 1393/12/29

Expected recruitment end date

2015-09-20, 1394/06/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of benzocaine-contained tooth paste on relieving orthodontic pain

Public title

the effect of benzocaine-contained tooth paste in decreasing fixed orthodontic pain

Purpose

Supportive

Inclusion/Exclusion criteria

inclusion criteria: patients in leveling and alignment stage who report pain in previous visit; presence of 6-8 crowding; patient informed consent exclusion criteria: history of liver, kidney or allergy to local anesthesia; history of chronic pain and continuous administration of anti pain drugs; presence of dental or mucosal pain; presence of mucosal wound

Age

From **15 years** old to **20 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **33**

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

Dental Research Center, Research Institute of Dental Sciences of Shahid Beheshti University of Medic

Street address

Dental Faculty, Shahid Beheshti University of Medical Sciences, Daneshjou Boulevard, Evin

City

Tehran

Postal code

Approval date

2014-09-23, 1393/07/01

Ethics committee reference number

21

Health conditions studied

1

Description of health condition studied

pain perceived after fixed orthodontic appointment

ICD-10 code

Y70-Y82

ICD-10 code description

Medical devices associated with adverse incidents in diagnostic and therapeutic use

Primary outcomes

1

Description

pain

Timepoint

2 hours and 6 hours after appointment, at the night of appointment, at 10am and 6pm on second and third day and on 10am on 7th day

Method of measurement

visual analogue scale (VAS) questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

benzocaine group: 5% benzocaine is added to a commercially available toothpaste, along with 0.075% Aspartam in order to mask benzocaine taste. each patient is given a toothpaste and asked to brush his/her teeth immediately after appointment, after breakfast and lunch and before sleep for 3 days. meanwhile, they are asked to mark their pain in a 0-100 scale, 2hours and 6hours after appointment, the same night before sleep, 10am and 6pm in second and third day and 10am at 7th day.

Category

Treatment - Drugs

2

Description

placebo group: a commercially available toothpaste is filled in identical tube as benzocaine tooth paste and is given to patients. patients are asked to use this toothpaste immediately after appointment, after breakfast and lunch and before sleep for 3 days. they are asked to mark their pain in a 0-100 scale 2 hours and 6 hours after appointment, at the same night before sleep, at 10am and 6pm on second and third day and at 10am on 7th day.

Category

Placebo

3

Description

control group: the patients are given a questionnaire with a 0-100 scale to mark their pain 2hours and 6 hours after appointment, at the same night before sleep, at 10am and 6pm on second and third day, at 10am on 7th day.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

orthodontic department at dental faculty, Shahid Beheshti University of Medical Sciences

Full name of responsible person

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Dental Research Center, Research Institute of Dental Sciences of Shahid Beheshti University of Medic

Full name of responsible person

Dr Asghar Ebadifar

Street address

Dental Faculty, Shahid Beheshti University of Medical Sciences, Daneshjou Boulevard, Evin

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Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Dental Research Center, Research Institute of Dental Sciences of Shahid Beheshti University of Medic

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

Sepideh Soheilifar

Position

postgraduate student (resident) of orthodontic department

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Orthodontic department Shahid Beheshti University of Medical Sciences

Full name of responsible person

Ladan Eslamian

Position

Professor at orthodontic department

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Full name of responsible person

Sepideh Soheilifar

Position

Other areas of specialty/work

Street address

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Phone

00

Fax

Email

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