

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The comparison of the effect of 5% naproxen gel and the placebo gel on reduction of fixed orthodontic pain after elastic separator placement; a randomized clinical trial study

Protocol summary

Summary

(1) Objectives: The study of 5% naproxen gel in fixed orthodontic pain reduction after elastic separator placement (2) Design: Randomized clinical trial, double blind, split mouth, use of placebo gel in control group, pilot and main study, 30 patients (3) Setting and conduct: The aim of doing the pilot study is assessment of durability, adherence, taste, analgesic effect (to determine which of 3 gels containing 1%, 2% and 4% carbomer has the best adherence and drug relief) and the correct way of using gels. Volunteer patients who cooperate in the pilot study would not be involved in the main study. (4) Sample population: Men and female with 14-20 year old of ages that need bilateral elastic separators for molar banding at the beginning of fixed orthodontic treatment and they present pain after separator placement. Patients who do not use gels or do not complete the questionnaire forms will be omitted from the study. (5) Interventions: Each patient will receive one drug containing gel and one placebo gel (the containers are similar and neither the patient nor the Distributor knows the bottles content). Each patient randomly places gel A in one quadrant and the other gel at another quadrant of the jaw. They are instructed by the trained distributor how to use gels every 8 hour up to 3 days after separator placement (first use of the gels will be just after separator placement in the office.) . (6) Main outcome: Pain; patients will represent their pain with Visual Analogue Scale in the questionnaire form at 2 and 6 hours after separator placement (after first use of the gels) and at 10 A.M. and 6 P.M. at days 2, 3 and 7 after separator placement.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016010716466N4**

Registration date: **2016-03-07, 1394/12/17**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-03-07, 1394/12/17

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

Investigator

Expected recruitment start date

2016-01-20, 1394/10/30

Expected recruitment end date

2016-04-21, 1395/02/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of the effect of 5% naproxen gel and the

placebo gel on reduction of fixed orthodontic pain after elastic separator placement; a randomized clinical trial study

Public title

prevention of orthodontic pain

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Men and female with 14-20 year old of ages; patients have no pain in teeth and gingiva at the beginning of study.; presence of tight contact between first molar with adjacent teeth and clinician needs to place bilateral elastic separators for molar banding and there is no space between the teeth in the jaw.; Patients are without posterior open bite and the first molars should have antagonist teeth in the opposite jaw.; patients present pain after separator placement.

Exclusion criteria: Patients who do not use naproxen gel and placebo gel will be omitted from the study.; patients who do not complete all parts of the questionnaire forms will be omitted from the study.; patients who use other analgesic drugs during the study will be omitted.; removal of any of separators

Age

From **14 years** old to **20 years** old

Gender

Both

Phase

2-3

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 Science, School Of Dentistry

Street address

The Research center, the forth floor, School Of Dentistry, Shahid Beheshti University of Medical Science, Evin, Shahid Chamran highway, Tehran, Iran

City

Tehran

Postal code

1983969411

Approval date

2014-03-08, 1392/12/17

Ethics committee reference number

598

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

The effect of 5% naproxen gel on orthodontic pain reduction

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Pain after orthodontic separator placement

Timepoint

2hours after first use, 6 hours after first use, 10A.M and 6 P.M on days 2,3 and 7 after separator placement

Method of measurement

Visual Analogue Scale

Secondary outcomes

empty

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

Naproxen gel, 5%, every 8 hours up to 3 days

Category

Prevention

2**Description**

Placebo gel, every 8 hours, up to 3 days

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Orthodontic clinic of Ladan Eslamian

Full name of responsible person

D.M.D., M.S. Ladan Eslamian

Street address

No:43, Satari Blvd, Valiasr St., kavosiye town,

Tehran, Iran

City

Tehran

2

Recruitment center

Name of recruitment center

Behfar dental clinic, related to School of Dentistry,
Shahid Beheshti University of Medical Science

Full name of responsible person

D.D.S., M.S. Mohammad Behnaz

Street address

Behfar dental clinic, Gas station, Pol bus station,
Damavand St., Hakimiyeh, Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Science, School
of Dentistry, Orthodontic department

Full name of responsible person

D.D.S., M.S. Ladan Eslamian

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No:43, Satari Blvd, Valiasr St., kavosiye, Tehran, Iran

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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 Science, School of
Dentistry, Orthodontic department

Proportion provided by this source

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

2

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Science, School
of Dentistry

Full name of responsible person

D.D.S., Azade Kianipour

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No. 3, Golestan Avenue, North Golestan St.,
Karmandan town, Kermanshah, Iran

City

Kermanshah

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 Science, School of
Dentistry

Proportion provided by this source

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 Science, School
of Dentistry

Full name of responsible person

Azade Kianipour

Position

D.D.S.

Other areas of specialty/work

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Full name of responsible person

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Position

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Person responsible for updating data

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Other areas of specialty/work
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Kermanshah

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