

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 May 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., kavooosiyeh 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., Hakimiye, Tehran, Iran

**City**

Tehran

**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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**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

**Street address**

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

**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.

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**Full name of responsible person**

Ladan Eslamian

**Position**

D.M.D. , M.S.

**Other areas of specialty/work**

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No. 3, Golestan Avenue, North Golestan St.,  
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**City**

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*