

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 May 2026

### The comparison of the effect of 5% naproxen patch and the placebo patch on reduction of fixed orthodontic pain after elastic separator placement

#### Protocol summary

##### Study aim

Assessment of the effect of 5% naproxen patch on post fixed orthodontic pain after elastic separator placement

##### Design

30 patients who need bilateral elastic separators for molar banding at the beginning of fixed orthodontic treatment and they present pain after separator placement are chosen and randomly divided into two groups of control and intervention. The containers and the color of placebo and naproxen patches are similar and the patient does not know the bottles' content to set the study blind

##### Settings and conduct

Study is done at personal and school related clinic, about orthodontic pain prevention, randomized and single blind. Patients, person who delivers patches to patient and statistic analyst are blind by not knowing patches content and their similar appearance. Each patient randomly places patch A in one quadrant and the other patch at another quadrant of the jaw while does not know the patch's content. They are instructed by the trained distributor how to use patches every 8 hour up to 3 days after separator placement (first use of the patches will be just after separator placement in the dental office.)

##### Participants/Inclusion and exclusion criteria

Entry conditions: Male 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. The first molars should have antagonist teeth in the opposite jaw. Patients are without posterior open bite. Patients present pain after separator placement. Not entry conditions: using naproxen is contraindicated in patients.

##### Intervention groups

Each patient will receive one drug containing patches and one placebo patches (the containers and the color of the patches are similar and the patient does not know the bottles' content to set the study blind). Each patient

randomly places patch A in one quadrant and the other patch at another quadrant of the jaw while does not know the patch's content. They are instructed by the trained distributor how to use patches every 8 hour up to 3 days after separator placement (first use of the patches will be just after separator placement in the dental office.)

##### Main outcome variables

degree of Primary Pain after orthodontic separator placement.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20140203016466N5**  
Registration date: **2018-01-21, 1396/11/01**  
Registration timing: **registered\_while\_recruiting**

Last update: **2018-01-21, 1396/11/01**

Update count: **0**

##### Registration date

2018-01-21, 1396/11/01

##### 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

Vice chancellor for research, Shahid Beheshti University of

Medical Sciences researchers: dr. Ladan Eslamian dr.  
Nazila Akbarianrad dr. seyed alireza mortazavi

**Expected recruitment start date**

2017-10-02, 1396/07/10

**Expected recruitment end date**

2018-02-20, 1396/12/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The comparison of the effect of 5% naproxen patch and the placebo patch on reduction of fixed orthodontic pain after elastic separator placement

**Public title**

prevention of orthodontic pain

**Purpose**

Prevention

**Inclusion/Exclusion criteria****Inclusion criteria:**

Male 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. the first molars should have antagonist teeth in the opposite jaw. Patients are without posterior open bite. patients present pain after separator placement.

**Exclusion criteria:**

using naproxen is contraindicated in patients.

**Age**

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

**Gender**

Both

**Phase**

1-2

**Groups that have been masked**

- Participant
- Care provider
- Data analyser

**Sample size**

Target sample size: **30**

More than 1 sample in each individual

Number of samples in each individual: **2**

buccal gingiva of right and left first molar

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

randomization was done in common method, personal and with quins.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

the containers and the color of the patches are similar and both the patient and the person who delivers the patches to patients and gets the questionnaires do not know the bottles' content to set the study blind

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of 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

**Province**

Tehran

**Postal code**

1983969411

**Approval date**

2016-02-10, 1394/11/21

**Ethics committee reference number**

IR.SBMU.RIDS.REC.1394.115

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

pain after orthodontic treatment

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

degree of Primary Pain after orthodontic separator placement

**Timepoint**

2hours , 6 hours and 24 hours, 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

placebo patch, every 8 hours up to 3 days

### Category

Placebo

## 2

### Description

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

### Category

Prevention

## 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., kavooziye town,  
Tehran, Iran

##### City

tehran

##### Province

Tehran

##### Postal code

1968953941

##### Phone

+98 21 2990 2304

##### Email

ladan.eslamian@sbmu.ac.ir

### 2

#### Recruitment center

##### Name of recruitment center

ghazi tabatabayi dental clinic, related to School of  
Dentistry, Shahid Beheshti University of Medica

##### Full name of responsible person

D.D.S., M.S. Mohammadreza badiiee

##### Street address

Ghazi Tabatabayi dental clinic, Farokhi Yazdi Sq, 8th  
Negarestan St, Pasdaran, Tehran, Iran

##### City

tehran

##### Province

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##### Postal code

1664718513

##### Phone

+98 21 2285 5551

##### Email

mohammadreza.badiiee@yahoo.com

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Shahid Beheshti University of Medical Sciences

#### Full name of responsible person

Afshin Zarghi

#### Street address

the research center, School Of medicine, Shahid  
Beheshti University of Medical Science, Evin, Shahid  
Chamran highway, Tehran, Iran

#### City

tehran

#### Province

Tehran

#### Postal code

1985717434

#### Phone

+98 21 2243 9951

#### Email

zarghi@sbmu.ac.ir

### 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

20

### Public or private sector

Public

### Domestic or foreign origin

Domestic

### Category of foreign source of funding

empty

### Country of origin

### Type of organization providing the funding

Academic

## 2

### 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

#### Street address

The Orthodontic department, the third floor, School Of  
Dentistry, Shahid Beheshti University of Medical  
Science, Evin, Shahid Chamran highway, Tehran, Iran

#### City

tehran

#### Province

Tehran

#### Postal code

1983963113

#### Phone

+98 21 2990 2304

#### Email

ladan.eslamian@sbmu.ac.ir

### 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**

80

**Public or private sector**

Private

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding***empty***Country of origin****Type of organization providing the funding**

Persons

**Person responsible for general inquiries****Contact****Name of organization / entity**

Shahid Beheshti University of Medical Science

**Full name of responsible person**

Nazila Akbarianrad

**Position**

Doctor of Dental surgery

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Dentistry

**Street address**

No4, Sherafat alley, 11th street, Asad abadi street , Tehran

**City**

tehran

**Province**

Tehran

**Postal code**

1433763648

**Phone**

+98 21 8870 6783

**Fax****Email**

rad.nazi@ymail.com

**Web page address****Street address**

The Orthodontic department, the third floor, School Of Dentistry, Shahid Beheshti University of Medical Science, Evin, Shahid Chamran highway, Tehran, Iran

**City**

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**Province**

Tehran

**Postal code**

1983963113

**Phone**

+98 21 2990 2304

**Fax****Email**

ladan.eslamian@sbmu.ac.ir

**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Nazila Akbarianrad

**Position**

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**Postal code**

1433763648

**Phone**

+98 21 8870 6783

**Fax****Email**

rad.nazi@ymail.com

**Web page address****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Ladan Eslamian

**Position**

Doctor of Medicine in Dentistry; orthonotist

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available