

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

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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

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Province

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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

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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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

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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

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

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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

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

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

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Position

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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