

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

The Effect of Naproxen Patch on Relieving Orthodontic Pain by Evaluation of VAS and IL-1 β Inflammatory Factor: A split-mouth study

Protocol summary

Study aim

Determine the effect of Naproxen patch on relieving orthodontic pain by evaluation of VAS and IL-1 β inflammatory factor

Design

Split-mouth triple-blind clinical trial

Settings and conduct

In this split-mouth triple-blind clinical trial, for 40 patients following separation, 5% Naproxen or placebo patches were randomly placed on the upper right or left first molars every 8 hours. Pain intensity scores were determined on 2 & 6 hours, sleep time, 24 hours, days 2, 3 and 7 by the patients using 100 mm VAS. Levels of IL-1 β in GCF were evaluated by ELISA at baseline, 1 and 24 hours and 7 days. Paired samples t and two-way repeated measures ANOVA analysis of variance tests with a significance level of 0.05 were applied.

Participants/Inclusion and exclusion criteria

The inclusion criteria were: Generally healthy patients, No periodontal or endodontic disease, Presence of bilateral first and second maxillary molars and second maxillary premolars, Tight posterior teeth contacts with no spacing, Presence of antagonist teeth without posterior open bite, No psychologic or mental disorder. Patients who did not participate in the follow-up sessions, had no pain on both sides, took systemic or topical painkillers except prescribed patches, removed separators, did not use patches as prescribed, and did not fill VAS questionnaire on time or lacked cooperation were excluded.

Intervention groups

5% Naproxen or placebo patches were randomly placed on the upper right or left first molars every 8 hours.

Main outcome variables

The pain related to the orthodontic tooth movement is common and cause dissatisfaction and discomfort. The present study aimed to compare the efficacy of Naproxen patch in pain control during orthodontic tooth separation by the Visual Analogue Scale (VAS) and

Interleukin 1 β (IL-1 β) levels of Gingival Crevicular Fluid (GCF).

General information

Reason for update

Acronym

VAS. IL

IRCT registration information

IRCT registration number: **IRCT20140203016466N7**

Registration date: **2018-04-30, 1397/02/10**

Registration timing: **retrospective**

Last update: **2018-04-30, 1397/02/10**

Update count: **0**

Registration date

2018-04-30, 1397/02/10

Registrant information

Name

Ladan Eslamian

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 21 2240 3010

Email address

ladan.eslamian@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-12-25, 1396/10/04

Expected recruitment end date

2018-04-24, 1397/02/04

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Naproxen Patch on Relieving Orthodontic Pain by Evaluation of VAS and IL-1 β Inflammatory Factor: A split-mouth study

Public title

The Effect of Naproxen Patch on Relieving Orthodontic Pain by Evaluation of VAS and IL-1 β Inflammatory Factor

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Generally healthy patients, No periodontal or endodontic disease, Presence of bilateral first and second maxillary molars and second maxillary premolars, Tight posterior teeth contacts with no spacing, Presence of antagonist teeth without posterior open bite, No psychologic or mental disorder.

Exclusion criteria:

Patients who did not participate in the follow up sessions, had no pain on both sides, took systemic or topical painkillers except prescribed patches, removed separators, did not used patches as prescribed, and did not fill VAS questionnaire on time or lacked cooperation were excluded.

Age

From **22 years** old to **40 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **40**

More than 1 sample in each individual

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

In each person, maxillary first molar of one side was considered as control, and another side as test group.

Randomization (investigator's opinion)

Not randomized

Randomization description**Blinding (investigator's opinion)**

Triple blinded

Blinding description

Neither the participants nor the researchers nor the person worked with Elisa reader nor the person analyzed data know which subjects received a particular treatment

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 Sciences

Street address

Shahid Beheshti Dental School, Evin Blv., Velenjak St., Tehran

City

Tehran

Province

Tehran

Postal code

4413667666

Approval date

2016-04-24, 1395/02/05

Ethics committee reference number

ir.sbm.u.rids.rec.1395.265

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

Effect of Naproxen Patch on Relieving Orthodontic Pain by Evaluation of VAS and IL-1 β Inflammatory Factor

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

-Patch type -Time

Timepoint

2 & 6 hours, sleep time, 24 hours, days 2, 3 and 7 day

Method of measurement

Visual Analogue Scale

Secondary outcomes

empty

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

Intervention group: Naproxen patch

Category

Treatment - Drugs

2

Description

Control group: Placebo patch

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Dental School

Full name of responsible person

Yasamin Babae Hemmati

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

100

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

Person responsible for general inquiries

Contact

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Yasamin Babae Hemmati

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

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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 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