Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Analgesic Efficacy of Ketoprofen Transdermal Patch Versus Ibuprofen Tablet on Post-Endodontic Pain in Patients with Irreversible Pulpitis – A Randomized Clinical Trial

Protocol summary

Study aim

Efficacy evaluation of transdermal ketoprofen patch on post-endodontic moderate to severe pain in single visit treatment of first/second mandibular molar with irreversible pulputis

Design

A randomized, double-blind, parallel group, controlled clinical trial, phase 2. 54 patients divided to 2 groups by stratified permuted blocks method.

Settings and conduct

Patients refer to endodontic section of dental school in Shahid Beheshti University of Medical Sciences receive post-operative patches or tablets to use every 6 hrs in 1 day. Patients pain intensity is measured before the operation and postoperatively in 0, 2, 4, 8,12, 24 and 48 hrs by Numeric Rating Scale. Collected data are analysed by Two way repeated measure ANOVA. all drugs are in unclear and sealed envelops and The investigator, dentist, data collector and analyzer are blinded in this study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age 18-65 years , ASA I physical status, first/second maxillary/mandibular molar with irreversible pulpitis, Exclusion criteria: any systemic disorders, using any analgesic drug in the past 12 hrs, gastrointestinal diseases or allergy to NSAIDS, allergy to local anesthetic drugs or sulfite.not being able to give informed consent or to read and pregnant or breastfeeding women. inappropriate teeth for restoration or teeth with severe periodontal disease, swelling or fistula or spontaneous pain. Exit criteria include disability in patient's fallow-up, inappropriate endodontic treatment and using other analgesics drugs.

Intervention groups

In the first intervention group, a transdemal ketoprofen patch is applied every 6 hours for 1 day after root canal treatment. In the second intervention group, ibuprofen is used every 6 hours for 1 day after root canal treatment.

Main outcome variables

Post-operative pain control in root canal treatment using ketoprofen patch or ibuprofen tablet

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190716044230N1**
Registration date: **2020-04-21, 1399/02/02**
Registration timing: **prospective**

Last update: **2020-04-21, 1399/02/02**
Update count: **0**

Registration date

2020-04-21, 1399/02/02

Registrant information

Name

Saeede Zadsirjan

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2241 3896

Email address

s_sirjani@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-22, 1399/07/01

Expected recruitment end date

2021-01-20, 1399/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Analgesic Efficacy of Ketoprofen Transdermal Patch Versus Ibuprofen Tablet on Post-Endodontic Pain in Patients with Irreversible Pulpitis – A Randomized Clinical Trial

Public title

Analgesic Efficacy of Ketoprofen Transdermal Patch Versus Ibuprofen Tablet on Post-Endodontic Pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients whom their physical status is classified as ASA I Mandibular first/second molar diagnosed as irreversible pulpitis with moderate to severe pain Positive response to electric pulp test, lingering pain to cold test which validate the diagnosis of irreversible pulpitis for each tooth

Exclusion criteria:

Having any systemic disorders, gastrointestinal disease or allergy which interfere with NSAIDS Allergy to local anesthesia drugs or sulfite Teeth that are not appropriate to be restorated or teeth with severe periodontal disease which are not suitable for endodontic treatment Patients with swelling or fistula Using any analgesic drug in the past 12 hours Spontaneous pain which requires emergency treatment Not being able to give informed consent or not being able to read and write Pregnant or breastfeeding women Exit criteria include disability (for any reason) in patient's fallow-up, inappropriate endodontic treatment or a two visit treatment and using other analgesics along with the study drugs.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **54**

Randomization (investigator's opinion)

Randomized

Randomization description

Method of randomization: block Unit of randomization: stratified Randomization strata: sex, teeth(first molar/second molar) Tools used in randomization: sealed envelops How the random sequence was built: permutation Allocation concealment: all the drugs are packed in same unclear sealed envelops which is not distinguishable for the researcher. This process is done by a third person that is unaware of the object and protocol of the study.

Blinding (investigator's opinion)

Double blinded

Blinding description

Dentist: he is not aware of the randomization and can not distinct drug packs because of their same appearance. principal investigator and data collectors: are not aware of the randomization. Outcome assessors: are not aware of the randomization.

Placebo

Not 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, Daneshjou blvd, Velenjak, Tehran

City

Tehran

Province

Tehran

Postal code

1983969411

Approval date

2020-01-28, 1398/11/08

Ethics committee reference number

IR.SBMU.DRC.REC.1398.226

Health conditions studied

1

Description of health condition studied

Irreversible pulpitis (dental)

ICD-10 code

K04.99

ICD-10 code description

Other diseases of pulp and periapical tissues

Primary outcomes

1

Description

Pain intensity after root canal treatment

Timepoint

Pain measurement immediately after root canal

treatment and 2, 4, 8,12, 24 and 48 hours after treatment

Method of measurement

Numerical rating scale (NRS)

Secondary outcomes

empty

Intervention groups

1

Description

First Intervention group: Name of the drug: Ketoprofen, How to use: Skin patch (patches with the trademark Ketoclin from Sinsin pharm company), Patch concentration: 60 mg, Frequency: Every 6 hours, Duration: 24 hours. Additional Description: Patch Placement: Hairless areas on the arm or forearm

Category

Treatment - Drugs

2

Description

Second Intervention group: Name of the drug: Ibuprofen, How to use: Oral tablets (Made by Tehran chemie company), Tablet concentration: 400 mg, Frequency: Every 6 hours, Duration: 24 hours.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dental faculty of Shahid Beheshti university of medical sciences

Full name of responsible person

Saeede Zadsirjan

Street address

Endodontic Department, Shahid Beheshti Dental school, Daneshjou Blvd, Velenjak

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DentalSchoolInfo@sbmu.ac.ir

Web page address

http://dentistry.sbmu.ac.ir/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Azita Tehranchi

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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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Saeede Zadsirjan

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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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