

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

Evaluation the effect of intraligamentary injection of the Lornoxicam on the post-operative endodontic pain in tooth with symptomatic irreversible pulpitis (Clinical Trial Study)

Protocol summary

Summary

Purpose: To determine the effect of intraligamentary injection of Lornoxicam on the intensity of post-operative endodontic pain in the tooth with symptomatic irreversible pulpitis on volunteer patients who are referred to the Endodontic department of Dental University of Islamic Azad University of Tehran in 2011-2012. Design of study: Placebo - Controlled Double Blind Clinical Trial Study. Inclusion criteria: Patients with first or second mandibular molars who need endodontic treatment and with clinical evidence of irreversible Pulpitis with moderate to severe pain. Exclusion criteria: Patients with allergy or contraindication toward non-opioid or opioid painkillers such as aspirin or NSAIDs; People who have a history of acute peptic ulcer, during the past 12 months; People who have bleeding problems or have been taking anticoagulant drugs over the past month; Patients who have taken opioid or non opioid or steroid pain killers, antidepressants or sedative drugs. Forty qualified samples (initial estimate which will be come more accurate after the pilot study on 6 patients) will be divided randomly in two groups which both will have an inferior Alveolar injection and before the beginning of the treatment the primary group will receive an injection of 0.4 mL (0.2 mL in mesio buccal and 0.2 mL in disto buccal) of Lornoxicam and the control group will be injected with 0.4 mL of 2% Lidocain with EP 1/180000 (as placebo). Then the patients' pain will be evaluated with visual Analogue Scale analysis (VAS) 0-9 mm in time intervals of 6, 12, 24 and 48 hours after the treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201108017191N1**

Registration date: **2011-10-09, 1390/07/17**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-10-09, 1390/07/17

Registrant information

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Recruitment status

Recruitment complete

Funding source

private

Expected recruitment start date

2011-09-23, 1390/07/01

Expected recruitment end date

2012-09-22, 1391/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effect of intraligamentary injection of the Lornoxicam on the post-operative endodontic pain in

tooth with symptomatic irreversible pulpitis (Clinical Trial Study)	Tehran Postal code 1946853314
Public title Evaluation the effect of the Lornoxicam on the post-operative endodontic pain	Approval date 2011-07-10, 1390/04/19
Purpose Treatment	Ethics committee reference number 440
Inclusion/Exclusion criteria Inclusion criteria: healthy (ASA I, II); Patients with first or second mandibular molars who need endodontic treatment; Vital tooth without a history of past endodontic treatment; Patients with clinical evidence of irreversible Pulpitis with moderate to severe pain; Patients without pre apical lesion and periodontal ligament enlargement more than 0.75-1mm on the x-ray images; Patients in the age group of 18-65 years old. Exclusion criteria: Pregnant or nursing; necrotic tooth; Patients with allergy or contraindication toward non-opioid or opioid painkillers such as aspirin or NSAIDs; People who have a history of acute peptic ulcer, during the past 12 months; People who have bleeding problems or have been taking anticoagulant drugs over the past month; Patients who have taken opioid or non opioid or steroid pain killers, antidepressants or sedative drugs.	Health conditions studied 1 Description of health condition studied Post operative endodontic pain ICD-10 code K08.8 ICD-10 code description Other specified disorders of teeth and supporting structures
Age From 18 years old to 65 years old	Primary outcomes
Gender Both	1 Description post oprative endodontic pain
Phase 2	Timepoint 6-12-24-48 hours after treatment
Groups that have been masked <i>No information</i>	Method of measurement Visual Analogue Scale (VAS 0-9mm)
Sample size Target sample size: 40	Secondary outcomes empty
Randomization (investigator's opinion) Randomized	Intervention groups
Randomization description	1
Blinding (investigator's opinion) Double blinded	Description Interventional group: After inferior Alveolar injection and before the beginning of the treatment the primary group will receive an injection of 0.4 mL (0.2 mL in mesio buccal and 0.2 mL in disto buccal) of Lornoxicam(1.6 mg)
Blinding description	Category Treatment - Drugs
Placebo Used	2
Assignment Parallel	Description Control group: wil be injected with 0.4 mL of 2% Lidocain with EP 1/180000
Other design features	Category Treatment - Drugs
Secondary Ids empty	Recruitment centers
Ethics committees	1
1	Recruitment center
Ethics committee	Name of recruitment center
Name of ethics committee Ethics committe of Dental School of Tehran Azad University	Dental School of Tehran Azad University
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City	

Full name of responsible person

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Azad University**Full name of responsible person**

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Dental Azad University

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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

Dental Azad University

Proportion provided by this source

100

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**Endodontic department, Dental School of Tehran
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Web page address**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