

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

Name

Mandana Abedi Tari

Name of organization / entity

Dental School of Tehran Azad University

Country

Iran (Islamic Republic of)

Phone

+98 912 397 7265

Email address

peymanm@dentiau.ac.ir

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 Approval date 2011-07-10, 1390/04/19 Ethics committee reference number 440
Public title Evaluation the effect of the Lornoxicam on the post-operative endodontic pain	Health conditions studied
Purpose Treatment	<u>1</u> 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
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.	Primary outcomes
Age From 18 years old to 65 years old	<u>1</u> Description post operative endodontic pain Timepoint 6-12-24-48 hours after treatment Method of measurement Visual Analogue Scale (VAS 0-9mm)
Gender Both	Secondary outcomes
Phase 2	empty
Groups that have been masked No information	Intervention groups
Sample size Target sample size: 40	<u>1</u> 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)
Randomization (investigator's opinion) Randomized	Category Treatment - Drugs
Randomization description	<u>2</u> Description Control group: will be injected with 0.4 mL of 2% Lidocain with EP 1/180000
Blinding (investigator's opinion)	Category Treatment - Drugs
Double blinded	Recruitment centers
Blinding description	<u>1</u>
Placebo	Recruitment center Name of recruitment center Dental School of Tehran Azad University
Used	
Assignment	
Parallel	
Other design features	
Secondary Ids	
empty	
Ethics committees	
<u>1</u>	
Ethics committee	
Name of ethics committee	
Ethics committee of Dental School of Tehran Azad University	
Street address	
No. 4, 10th alley, Pasdaran Ave	
City	

Full name of responsible person

Dr.Peyman Mehrvarzfar

Street address

No. 4, 10th alley, Pasdaran Ave

City

Tehran

Web page address

www.dentaliau.ir

Person responsible for scientific inquiries**Contact****Name of organization / entity**Endodontic department, Dental School of Tehran
Azad University**Full name of responsible person**

Dr Paymen Mehrvarzfar

Position

Assistant professor

Other areas of specialty/work**Street address**

No. 4, 10th alley, Pasdaran Ave

City

Tehran

Postal code**Phone**

+98 912 104 5805

Fax**Email**mani_tari@yahoo.com , mehrvarzfar@gmail.com ,
dr.p.mehrvarzfar@dentaliau.ir**Web page address**

www.dentaliau.ir

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

Dental Azad University

Full name of responsible person

Dr. Arash Azizi

Street address

10th neyestan, Pasdran Ave

City

Tehran

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
Azad University**Full name of responsible person**

Dr. Peyman Mehrvarzfar

Position

Assistant Professor

Other areas of specialty/work**Street address**

No. 4, 10th alley, Pasdaran Ave

City

Tehran

Postal code

1946853314

Phone

+98 912 104 5805

Fax**Email**mani_tari@yahoo.com , mehrvarzfar@gmail.com ,
dr.p.mehrvarzfar@dentaliau.ir**Person responsible for updating data****Contact****Name of organization / entity**

Dental School of Tehran Azad University, Tehran, Iran

Full name of responsible person

Mandana Abedi Tari

Position**Other areas of specialty/work****Street address**

No. 4, 10th alley, Pasdaran Ave

City

Tehran

Postal code**Phone**

+98 912 397 7265

Fax**Email**

mani_tari@yahoo.com

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