Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of anesthetic efficacy lidocain / epinephrine with and without sufentanil for intra ligamentary injection in the mandibular posterior tooth with irreversible pulpitis

Protocol summary

Summary

The aim of this study was to compare the effects of Lidocaine/epinephrine with and without Sufentanil on the rate of anesthesia after supplemental intraligamentary injection (PDL) in irreversible pulpitis teeth. Qualified individuals were selected among people referred to the endodontic part of Azad University of Tehran; the study was conducted with a double blind placebo control clinical trial. 60 patients between 18-65 years of age, which had mandibular posterior teeth in clinical diagnosis with irreversible pulpitis, received injections of normal alveolar block. In all those who had numbness around the lips, maximum output response to pulp testing, 15 minutes after receiving infra alveolar block, it was performed the starting of preparing the cavity, and those who had moderate to severe pain, were injected with intra ligaments supplements. They reported their pain with Visual Analogue scale(Vas), before the injection, immediately after injection, access cavity, Pulpotomy and putting the initial file and pulpectomy. The volunteers were divided randomly in to two groups namely control group (lidocaine/epinephrine) and case group (combined solution of lidocaine/epinephrine & sufentanil). The injection was done by 0.5-inch and 27 needle gauge which was connected to the pressure syringes. Injection sites were on mesiobuccal and Disto buccal location. Depth of anesthesia was recorded by electric pulp tester (EPT) in 1 and 5, 9, 13 and 17 minutes.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201110137790N1**
Registration date: **2012-01-25, 1390/11/05**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2012-01-25, 1390/11/05

Registrant information

Name
Hengameh Mohammadi
Name of organization / entity
Dentistry Azad Univercity of Tehran
Country
Iran (Islamic Republic of)
Phone
+98 21 2212 3426
Email address
peymanm@dentliau.ac.ir

Recruitment status

Recruitment complete

Funding source

Islamic Azad dental university of Tehran

Expected recruitment start date

2010-10-14, 1389/07/22

Expected recruitment end date

2011-07-01, 1390/04/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of anesthetic efficacy lidocain / epinephrine with and without sufentanil for intra ligamentary injection in the mandibular posterior tooth with irreversible pulpitis

Public title

Effect of sufentanil on the severe of anesthesia

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: patients with VITAL mandibular molars; patients with dental with irreversible pulpits clinical evidence; those candidates who suffer from moderate to severe pain; patients who signed consent form; those who felt with lip edge anesthesia after injection of infra alveolar (INA) and those who responded positively to output maximum of pulp tester. Exclusion criteria: Systemic disease; pregnancy and lactation; age: Patients under the age of 18 years and older than 65 years; infectious diseases; moderate to advanced periodontal disease; necrotic teeth; sensitivity OPIOIDs, Benzodiazepines, Barbiturate or use of them in the past 48 hours; those without lip edge anesthesia after injection of infra alveolar (INA), and those, does not respond to maximum output pulp tester after injection of INA.

Age

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

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Islamic Azad dental university of Tehran

Street address

Islamic Azad university, dentistry department, 10th neistan, Pasdaran

City

Tehran

Postal code

Approval date

2010-01-05, 1388/10/15

Ethics committee reference number

18081

Health conditions studied

1

Description of health condition studied

irreversible pulpitis

ICD-10 code

K04.0

ICD-10 code description

Pulpitis

Primary outcomes

1

Description

intensity of the pain

Timepoint

before intervention,during the intervention,in the immediately after injection,access cavity,initial file,pulpotomy,pulpectomy

Method of measurement

with visual analogue scale(VAS)

2

Description

depth of anesthesia

Timepoint

before intervention,during the intervention,in the 1,5,9,13,17th minuths

Method of measurement

with electric pulp tester

Secondary outcomes

empty

Intervention groups

1

Description

second group:0/4 ml lidocain with epinephrine and0/4 ml sufentanil (0/04 µg)

Category

Treatment - Drugs

2

Description

first group:0/4 ml lidocain %2 with epinephrine,0/4 ml salin

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Islamic Azad dental Univercity of Tehran

Full name of responsible person
Dr. Peyman Mehrvarz far

Street address
Islamic Azad university, dentistry department, 10th neistan, Pasdaran

City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Islamic Azad dental university of Tehran

Full name of responsible person
Dr. Arash Azizi

Street address
Islamic Azad university, dentistry department, 10th neistan, Pasdaran

City
Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Islamic Azad dental university of Tehran

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
Islamic Azad dental university of Tehran

Full name of responsible person
Dr. Peyman Mehrvarz far

Position
Associate Professor

Other areas of specialty/work

Street address
Islamic Azad university, dentistry department, 10th neistan, Pasdaran

City
Tehran

Postal code

Phone
+98 21 2256 4571

Fax

Email
lpeymanm@dentliau.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Islamic Azad dental Univercity of Tehran

Full name of responsible person
Peyman Mehrvarz far

Position
assosiate professor

Other areas of specialty/work

Street address
Islamic Azad university, dentistry department, 10th neistan, Pasdaran

City
Tehran

Postal code

Phone
+98 21 2256 4571

Fax

Email
lpeymanm@dentliau.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Islamic Azad dental university of Tehran

Full name of responsible person
Dr. Peyman Mehrvarz far

Position
Associate Professor

Other areas of specialty/work

Street address
Islamic Azad university, dentistry department, 10th neistan, Pasdaran

City
Tehran

Postal code

Phone

Fax

Email

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