Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Jul 2026

Evaluation the effect of admixture of clonidine and lidocaine in comparison with epinephrine and lidocaine on postoperative pain after single visit root canal therapy of mandibular molars with irreversible pulpitis

Protocol summary

Summary

The purpose of this study is to evaluate the efficacy of admixture of clonidine and lidocaine in comparison with admixture of epinephrine and lidocaine on postoperative pain after single visit root canal therapy of mandibular molars with irreversible pulpitis. A randomized double-blind study will designed. One hundred emergency patients who attended faculty of dentistry, Isfahan university of medical sciences in the range of 18-60 years old and physical status ASA I with at least one first or second mandibular molars having diagnosed irreversible pulpitis, will involved in this study. Patients taking beta-blockers or any opioids preoperatively, drug abusers, pregnant or nursing mothers, those with a contraindication for the use of clonidine and those known to be allergic will excluded from the study. Patients randomly received 1.8 mL of 2% lidocaine with clonidine (15 µg/mL) or 1.8 mL of 2% lidocaine with epinephrine (12.5 µg/mL), using a conventional IANB technique. Root canal therapy will done in a single visit appointment. Patients will asked to recorded their pain on a Heft-Parker visual analogue scale (VAS) at 6, 12, 24, 36, 48, and 72 hours after treatment. They also will asked to record the number of analgesic tables that they will use.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201512076578N33**
Registration date: **2015-12-18, 1394/09/27**
Registration timing: **na**

Last update:
Update count: **0**

Registration date

2015-12-18, 1394/09/27

Registrant information

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Recruitment status

Not enough for processing

Funding source

Vice Chancellor for research, Isfahan University of Medical Sciences

Expected recruitment start date

2015-12-22, 1394/10/01

Expected recruitment end date

2006-03-21, 1385/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effect of admixture of clonidine and lidocaine in comparison with epinephrine and lidocaine on postoperative pain after single visit root canal therapy of mandibular molars with irreversible pulpitis

Public title

The effect of admixture of clonidine and lidocaine as dental anesthesia solution on postoperative pain

Purpose

Prevention

Inclusion/Exclusion criteria

The inclusion criteria: 18 years of age up to 60; in good health(ASA I (classification of the American Society of Anesthesiologists)); having at least one mandibular molar teeth with irreversible pulpitis criteria The exclusion criteria: Patients taking beta-blockers or being medicated with any opioids preoperatively; drug abusers; pregnant or nursing mothers; those with a contraindication for the use of clonidine; those known to be allergic to clonidine; those with orofacial infection/inflammation

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Five-digit random numbers are chose by using computer random number and are written on a label on the anesthetic solutions. And also each one will kept in a separate sealed opaque envelope. All these procedure is done by a third person who has no clue and has not involved in the rest of the study. Patients with simple random sampling protocol choose the envelope to determine which anesthetic solution will be administered. Only the random number is used on the data collection sheets to further blind the experiment.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Department of Isfahan University of Medical Sciences

Street address

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City

Isfahan

Postal code

81723477

Approval date

2004-09-22, 1383/07/01

Ethics committee reference number

393430

Health conditions studied

1

Description of health condition studied

Irreversible pulpitis

ICD-10 code

KO4.0

ICD-10 code description

Diseases of pulp and periapical tissues, Pulpitis

Primary outcomes

1

Description

Pain

Timepoint

6, 12, 24, 36, 48, 72

Method of measurement

Heft-Parker visual analogue scale (VAS)

Secondary outcomes

empty

Intervention groups

1

Description

Control group : 1.8 mL of 2% lidocaine with epinephrine 1:80000 (L+Epi) at a concentration of 12.5 µg/mL (Persicaine, Darupakhsh, Tehran, Iran) applied by using conventional inferior alveolar nerve block injection technique.

Category

Treatment - Drugs

2

Description

Intervention group: 1.8 mL of 2% lidocaine with clonidine (L+Clo) at a concentration of 15 µg/mL applied by using conventional inferior alveolar nerve block injection technique.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Torabinejad research center
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Vice Chancellor for research of Isfahan University of Medical Sciences
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

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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