Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effect of Preoperative Alprazolam on the Success of Inferior Alveolar Nerve Block for Teeth with Irreversible Pulpitis

Protocol summary

Summary

Background: Success of inferior alveolar nerve (IAN) block reduces in patients with irreversible pulpitis. The purpose of this prospective, randomized, double-blind, placebo-controlled study was to evaluate the effect of preoperative administration of alprazolam on the success of the IAN block for teeth with irreversible pulpitis. Method: Sixty patients diagnosed with irreversible pulpitis of a mandibular molar randomly received, in a double-blind manner, identical capsules of either 0.50 mg alprazolam or placebo 45 minutes before the administration of a conventional IAN block. Access was begun 15 minutes after completion of the IAN block, and all patients had profound lip numbness. Success was defined as no or mild pain based on visual analog scale recordings during access preparation and initial instrumentation.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201203032541N3**
Registration date: **2012-03-22, 1391/01/03**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2012-03-22, 1391/01/03

Registrant information

Name
Masoud Saatchi
Name of organization / entity
School of Dentistry, Isfahan University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source
Isfahan University of Medical Sciences

Expected recruitment start date

2011-02-15, 1389/11/26

Expected recruitment end date

2012-02-29, 1390/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Preoperative Alprazolam on the Success of Inferior Alveolar Nerve Block for Teeth with Irreversible Pulpitis

Public title

Effect of Alprazolam on the Success of Inferior Alveolar Nerve (IAN) Block

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients with active pain in a mandibular molar; prolonged response to cold testing; Absence of any periapical radiolucency on radiographs; a vital pulp while access cavity preparation; ability to understand the use of pain scales. Exclusion criteria: patients were having allergy, sensitivity, to benzodiazepines; pregnant and breast feeding patients; patients who had taken sedation within 24 hours before the treatment - having pain in more than one mandibular

tooth - unable to give informed consent.

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

Gender
Both

Phase
3

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

1

Registry name
ClinicalTrials.gov

Secondary trial Id
NCT01546090

Registration date
2012-03-02, 1390/12/12

Ethics committees

1

Ethics committee

Name of ethics committee
The Ethics Committee of the Isfahan University of Medical Sciences

Street address
Isfahan University of Medical Sciences

City
Isfahan

Postal code
81746-73461

Approval date
2011-03-15, 1389/12/24

Ethics committee reference number
390553

Health conditions studied

1

Description of health condition studied
irreversible pulpitis

ICD-10 code
K08.8

ICD-10 code description
Toothache NOS

Primary outcomes

1

Description
the success rate of the IAN block

Timepoint
1 hour after alprazolam administration

Method of measurement
Heft-Parker visual analogue scale (pain scale)

Secondary outcomes

1

Description
anxity

Timepoint
before treatment initiation

Method of measurement
Corah dental anxity scale

2

Description
initial pain

Timepoint
before alprazolam administration

Method of measurement
Heft-Parker visual analogue scale (a pain scale)

Intervention groups

1

Description
placebo, 45 minutes before the administration of a conventional IAN block

Category
Placebo

2

Description
0.50 mg of alprazolam, 45 minutes before the administration of a conventional IAN block

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
School of Dentistry, Isfahan University of Medical Sciences

Full name of responsible person

Abbas Ali Khademi

Street address

School of Dentistry, Isfahan University of Medical Sciences

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Abbas Ali Khademi

Street address

School of Dentistry, Isfahan University of Medical Sciences

City

Isfahan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

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

Person responsible for general inquiries

Contact

Name of organization / entity

School of Dentistry, Isfahan University of Medical Sciences

Full name of responsible person

Abbas Ali Khademi

Position

Professor of Endodontics

Other areas of specialty/work

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Web page address

Person responsible for updating data

Contact

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