

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 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

Country

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

anxiety

Timepoint

before treatment initiation

Method of measurement

Corah dental anxiety 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

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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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Department of Endodontics, School of Dentistry, Isfahan University of Medical Sciences

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Person responsible for scientific inquiries

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School of Dentistry, Isfahan University of Medical Sciences

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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