Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jul 2026

A comparison of anesthetic efficacy of combined local anesthetic and ketamine in patients with irreversible pulpitis in the posterior mandibular teeth

Protocol summary

Summary

Forty patients with clinical signs and symptoms of irreversible pulpitis in one of their posterior mandibular teeth will enter the study upon completion of their medical history. Each patient will be randomly assigned to one of the study groups (the local anesthetic only group or the local anesthetic with ketamine group) and their primary pain score will be recorded. Each patient will recieve two dental cartridges injected with an inferior alveolar nerve block technique. The tooth will then be tested with a pulp tester and then a pulpectomy treatment will be carried out. Any pain experienced by the patient along with its stage will be recorded. The conventional treatment will be carried out for the patient.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138905024440N1**
Registration date: **2010-10-11, 1389/07/19**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2010-10-11, 1389/07/19

Registrant information

Name

Vahid Sakhaei manesh

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Dental School of Isfahan University of Medical Sciences

Expected recruitment start date

2010-08-01, 1389/05/10

Expected recruitment end date

2010-12-01, 1389/09/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparison of anesthetic efficacy of combined local anesthetic and ketamine in patients with irreversible pulpitis in the posterior mandibular teeth

Public title

A comparison of anesthetic efficacy of combined local anesthetic and ketamine in patients with irreversible pulpitis in the posterior mandibular teeth

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Patients aged 18-50 years, in healthy condition (ASA I or ASA II), having a posterior mandibular tooth (premolar or molar tooth) with a vital pulp and diagnosed as irreversible pulpitis, without severe periodontal disease, without any periapical pathological defect as seen in the radiograph of the tooth, without any contraindications for the drugs and substanses used in the study. Exclusion criteria: Patients showing signs of

pulp necrosis upon access cavity opening, patients showing any signs or symptoms of allergy or any adverse effects, patients refusing to continue at any stage point.

Age
From **18 years** old to **50 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **40**

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
Dental School Ethics Committee, Isfahan University of Medical Sciences

Street address
Vice Chancellor for Research of Dental School, Isfahan University of Medical Sciences

City
Isfahan

Postal code

Approval date
empty

Ethics committee reference number
388485

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
Pain

Timepoint
Before and 15 minutes after administration of the local anesthetic

Method of measurement
Visual Analogue Scale (VAS)

Secondary outcomes

1

Description
Pulpal anesthesia

Timepoint
Before and 15 minutes after administration of the local anesthetic

Method of measurement
Pulp tester

Intervention groups

1

Description
Two dental cartridges of 2% Articaine combined with 20mg of Ketamine

Category
Treatment - Drugs

2

Description
Two dental cartridges of 2% Articaine combined with 0.2ml normal saline

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Kaveh Dental Clinic

Full name of responsible person

Street address

City
Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice Chancellor for Research of Dental School, Isfahan

University of Medical Sciences

Full name of responsible person
Dr. Omid Savabi

Street address
Hezar Jarib Street

City
Isfahan

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 Dental School, 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
Dental School, Isfahan University of Medical Sciences

Full name of responsible person
Vahid Sakhaei manesh

Position
Student of DDS course

Other areas of specialty/work

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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