

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Effect of Preoperative Oral Ketamine in Comparison with Ibuprofen on Postoperative Endodontic Pain

Protocol summary

Summary

Ketamine hydrochloride is a well known general anesthetic. Low dose or sub-anesthetic doses of ketamine have been used effectively as either a primary analgesic or analgesic adjuvant in a variety of pain syndromes. The purpose of this study is to compare the effect of preoperative administration of oral ketamine, ibuprofen, and placebo in managing postendodontic pain. In this clinical trial, 51 patients with irreversible pulpitis are randomly assigned into 3 groups to receive, in a double-blind manner, a single dose of oral ketamine 0.5mg/kg, 600mg of ibuprofen, or placebo. Treatment is completed in one visit. Patients will record their pain levels on a visual analog scale, before and at 2, 4, 8, 12 and 24h after treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201009054697N1**

Registration date: **2010-12-07, 1389/09/16**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2010-12-07, 1389/09/16

Registrant information

Name

Ashkan Vakilizadeh

Name of organization / entity

School of Dentistry (Isfahan University of Medical Sciences and Islamic Azad University Khorasgan)

Country

Iran (Islamic Republic of)

Phone

+98 21 2621 4610

Email address

ashkanvakilizadeh@yahoo.com

Recruitment status

Recruitment complete

Funding source

School of Dentistry, Isfahan University of Medical Sciences and School of Dentistry, Islamic Azad University Khorasgan Branch

Expected recruitment start date

2010-12-11, 1389/09/20

Expected recruitment end date

2011-10-12, 1390/07/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Preoperative Oral Ketamine in Comparison with Ibuprofen on Postoperative Endodontic Pain

Public title

Effect of Ketamine on Postendodontic Pain

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: 1. Patient elects root canal therapy for pain originating from a first or second mandibular molar. 2. The diagnosis of irreversible pulpitis is confirmed by a chief complaint of spontaneous pain and cold test application causing an elevated and lingering pain response. 3. The patient presented with American Society of Anesthesiologists (ASA) I or II medical history. 4. Patient reads and understands questionnaires. 5. Patient reports spontaneous pain above 3cm on a VAS (0-10 cm) in past 24h. 6. Patient provides informed consent. Exclusion criteria: 1. Younger than 18 yr or

older than 65 yr. 2. Analgesic taken within the last 8h. 3. History of allergy to NSAIDs, ketamine or local anesthetics. 4. Current use of drugs contraindicated with NSAIDs or ketamine. 5. History of gastrointestinal (GI) disorders, renal or hepatic disease, hemorrhagic disorders, active asthma, poorly controlled diabetes mellitus, cardiovascular disease, increased ICP, intracranial mass lesions, ophthalmologic disorder or psychiatric disease. 6. The patient is pregnant or nursing. 7. Periradicular pathosis, other than a widened periodontal ligament. 8. No vital coronal pulp tissue on access. 9. Occurrence of any mistake during root canal therapy.

Age

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

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **51**

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

School of Dentistry, Islamic Azad University
Khorasgan Branch

Street address

University Blvd, Arqavanieh, Jey Street, Isfahan

City

Isfahan

Postal code

Approval date

2007-10-24, 1386/08/02

Ethics committee reference number

23810201852031

Health conditions studied

1

Description of health condition studied

Postoperative Endodontic Pain

ICD-10 code

K08.8, K04

ICD-10 code description

Other specified disorders of teeth and supporting structures - Toothache NOS and Pulpitis: acute

Primary outcomes

1

Description

Pain intensity

Timepoint

Before and at 2, 4, 8, 12 and 24h after treatment

Method of measurement

Visual Analog Scale

Secondary outcomes

1

Description

The need for additional medication

Timepoint

Until 24h after treatment

Method of measurement

Questionnaire

2

Description

Time to first request for rescue analgesic

Timepoint

Until 24h after treatment

Method of measurement

Questionnaire

3

Description

The number of rescue analgesic tablets taken

Timepoint

Until 24h after treatment

Method of measurement

Questionnaire

4

Description

The incidence of side effects

Timepoint

Until 24h after treatment

Method of measurement

Questionnaire

Intervention groups

1

Description

Oral suspension of ibuprofen, 600 mg, A single dose, 30 minutes before the initiation of treatment, Oral

Category

Prevention

2

Description

Placebo, A single dose, 30 minutes before the initiation of treatment, Oral

Category

Placebo

3

Description

Ketamine hydrochloride, 0.5mg/kg, A single dose, 30 minutes before the initiation of treatment, Oral

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Central Dental Clinic of Isfahan's Oil Industry

Full name of responsible person

Ashkan Vakilzadeh - Dentist (D.D.S.)

Street address

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

School of Dentistry, Islamic Azad University
Khorasgan Branch

Full name of responsible person

Abbasali Khademi - Full Professor

Street address

University Blvd, Arqavanieh, Jey Street, Isfahan

City

Isfahan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

School of Dentistry, Islamic Azad University Khorasgan
Branch

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 and School of Dentistry, Islamic Aza

Full name of responsible person

Ashkan Vakilzadeh

Position

Dentist (D.D.S.)

Other areas of specialty/work

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Person responsible for scientific inquiries

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Full name of responsible person

Ashkan Vakilzadeh

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Person responsible for updating data

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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