Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 Vakilzadeh

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

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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 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