

# 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 receive 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)

###### Phone

+98 31 1792 2869

###### Email address

sakhaei@dnt.mui.ac.ir

##### 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 substances 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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## Person responsible for scientific inquiries

**Contact**

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

**Full name of responsible person**

Dr. Abbasali Khademi

**Position**

MSc, Professor of Dental School, Isfahan University of Medical Sciences

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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*