

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jul 2026

### Evaluation of Postoperative Endodontic Pain in 60 lower molars under General Anaesthesia versus Local Anaesthesia

#### Protocol summary

##### Summary

The aim of this clinical trial study is the comparing of postoperative endodontic pain in 60 mandibular molars on 2013-14. Therefore a successful management of endodontic pain has become as one of the main dental objectives. The aim of the present study was to compare the postoperative endodontic pain in patients under general anaesthesia versus local anaesthesia. This study will be performed on a format of clinical trial on 60 patient. First and second mandibular molars with symptomatic pulpitis will be selected. 30 patients will be treated under general anaesthesia because of their fear, anxiety, or gag reflex. other 30 patients will be treated under local anaesthesia. This treatments no requires the patient's randomization. All teeth will be prepared using engine-driven rotary system in a Crown-down technique and fill using Lateral Condensation technique. Heft-Parker Visual Analog Scale will be used to measure the degree of pain at 6, 12, 24 and 48 hours after the treatment. The outcome will be assessed using variant analysis method.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2013061013619N1**

Registration date: **2013-09-07, 1392/06/16**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2013-09-07, 1392/06/16

##### Registrant information

###### Name

Ghader Feizi

##### Name of organization / entity

Isfahan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 1792 2812

##### Email address

feizi@dnt.mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Isfahan University of Medical Sciences

##### Expected recruitment start date

2013-06-22, 1392/04/01

##### Expected recruitment end date

2014-03-21, 1393/01/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of Postoperative Endodontic Pain in 60 lower molars under General Anaesthesia versus Local Anaesthesia

##### Public title

Clinical evaluation of the general and local anesthesia techniques on postoperative pain

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

( Inclusion criteria: age 60-20 years; no history of systemic diseases; especially lower molars with irreversible pulpitis) ( Exclusion criteria: history of a systemic disease; lack of anesthesia; the anesthesia group )

##### Age

From **20 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)

N/A

## Randomization description

## Blinding (investigator's opinion)

Single blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Isfahan Regional Bioethics Committee

##### Street address

University of Medical Sciences

##### City

Isfahn

##### Postal code

8174673461

#### Approval date

2012-10-15, 1391/07/24

#### Ethics committee reference number

392072

## Health conditions studied

### 1

#### Description of health condition studied

Irreversible pulpitis

#### ICD-10 code

K04

#### ICD-10 code description

pulpitis-irreversible

## Primary outcomes

### 1

#### Description

Degree of Pain

#### Timepoint

2,6,12,24 and 48 hours after procedure

## Method of measurement

Visual Analogues Scale

## Secondary outcomes

### 1

#### Description

prolonged recovery time

#### Timepoint

1,2,4,8 h

#### Method of measurement

Level of alertness and reaction to stimulates

## Intervention groups

### 1

#### Description

Patients will divided into two groups. In the first experimental group anesthesia will take in less than 2 hours. Requires the injection of drugs were as follows: Patients induction will perform using / kg mg 5 thiopental sodium (Nani Pharmaceuticals, India) and µg / Kg 1 Fentanyl (Aboureihan, Tehran, Iran) and mg / Kg 4/0 Atracurium (Aboureihan, Tehran, Iran) and will attach to Dragr anesthesia machine (Drager, Fabius, Germany) according to the setting of weights. Anesthesia maintain will perform with 50% oxygen (gas medicine, Isfahan, Iran) and nitrous oxide 50% (clinic, Isfahan, Iran). Also, after treatment with drugs will inject into the muscle relaxation Reverse mg / kg 4/0 neostigmine (drug Alborz - Iran) and mg / kg 2/0 atropine (Daroupakhsh - Iran), the patient will awaken and transfer to the recovery room.

#### Category

Treatment - Other

### 2

#### Description

we have not applicable in control group

#### Category

N/A

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Hospitalized Dentistry

##### Full name of responsible person

Ghader Feizi

##### Street address

Torabinejad Dental Research Center-Faculty of Dentistry - Isfahan University of Medical Sciences- St. Hezarjarib

##### City

Isfahan

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Isfahan university of Medical Sciences

**Full name of responsible person**

Dr.Omid Savabi

**Street address**

Department of Research and Technology, Building No. 4, Central Organ Of University, Isfahan university of Medical Sciences

**City**

Isfahan

**Grant name****Grant code / Reference number**

392072

**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**

Isfahan university of Medical Sciences

**Full name of responsible person**

Dr. Ghader Feizi

**Position**

Endodontist

**Other areas of specialty/work****Street address**

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**Web page address**

## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Isfahan university of Medical Sciences

**Full name of responsible person**

Dr. Masoud Saatchi

**Position**

Endodontist, Associate Prof.

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## Person responsible for updating data

**Contact****Name of organization / entity**

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**Full name of responsible person**

elham alsadat binandeh

**Position**

statistic expert of research center

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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*