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 pulpits 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, 12,24and 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

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Name of organization / entity

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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

Isafahn

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

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City

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Sponsors / Funding sources

1

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

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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