

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Clinical Trial of Comparison of the Effect of Premedication with Pharmapain, Dexamethasone and Placebo on Pain Severity after Administration of Anesthesia in Inferior Molar Teeth with Irreversible Pulpitis

Protocol summary

Summary

The aim of this study is to evaluate the effect of premedication with pharmapain and dexamethasone on the success rate of inferior alveolar nerve block in teeth with irreversible pulpitis. The patients are over eighteen years old, with irreversible pulpitis in one of the mandibular molars. Aggarwal's study is used to determine the volume of the subjects which consisted of 210 patients. Some of the inclusion criteria are patients over 18 with irreversible pulpitis in one of the mandibular molars with normal radiographic view. Some of the exclusion criteria are Hypersensitivity to lidocaine, Impossible to restore the teeth, Presence of a crown before the procedure, Internal or external resorption. All the patients take a capsule which has the same shape 30 minutes before anesthesia. The capsules contain Placebo (Lactose) or 400 mg pharmapain or 0.5 mg Dexamethasone. Then inferior alveolar nerve is blocked. After fifteen minutes, signs of soft tissue anesthesia will be evaluated. If the patient has no signs of anesthesia (s) he is excluded from the study. In patients with successful nerve block cold test and electric pulpal test will be carried out and pain scores evaluated with VAS. The tooth will be isolated and access cavity will be prepared. If the patient has pain during access cavity preparation, pain during pulp chamber entrance or pulp canal entrance, pain will be measured with VAS. No pain or mild pain will be considered as success and other pain intensities as failure. In this study, participants (patients) and researchers are blinded to the type of drugs. (Double - blind)

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014040417118N1**

Registration date: **2015-08-13, 1394/05/22**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-08-13, 1394/05/22

Registrant information

Name

Negar Moghaddam

Name of organization / entity

Tabriz University of Medical Science

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research ,Tabriz University of Medical Science

Expected recruitment start date

2014-08-23, 1393/06/01

Expected recruitment end date

2015-02-20, 1393/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical Trial of Comparison of the Effect of Premedication with Pharmapain, Dexamethasone and Placebo on Pain Severity after Administration of Anesthesia in Inferior Molar Teeth with Irreversible Pulpitis

Public title

The Effect of Pharmapain and Dexamethasone on Reducing Pain during Root Canal Therapy of Mandibular Teeth

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion Criteria: Age over than 18 years old; first or second Molar teeth with irreversible pulpitis; Normal peri-radicular status according to radiography. Exclusion Criteria: Hypersensitivity to lidocaine; Impossible to restore the teeth ; Presence of a crown before the procedure ; Internal or external resorption ; Teeth with open apices ;Breast-feeding ; Pregnancy; Use of analgesics 12 hours before treatment; No sign of soft tissue anesthesia.

Age

From **18 years** old to **45 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **210**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

To randomize the patients, each patient was assigned a number. Numbers were randomly divided into three groups. The numbers in each group were written on paper, and each one was kept in a separate sealed opaque envelope. Each patient was asked to choose one of the envelopes and was assigned to one of the groups on the basis of the number. In this study, participants (patients) and researchers are blinded to the type of drugs.(Double - blind)

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics in Research Committee ,Tabriz University of Medical science

Street address

International Relations Office, No 2 Central Building, Tabriz University of Medical Sciences, Golgasht Street, Tabriz, East Azerbaijan, Iran

City

Tabriz

Postal code

Approval date

2015-07-06, 1394/04/15

Ethics committee reference number

TBZMED.REC.1394.316

Health conditions studied

1

Description of health condition studied

Irreversible Pulpitis

ICD-10 code

K04

ICD-10 code description

Diseases of pulp and periapical tissues

Primary outcomes

1

Description

inferior alveolar nerve block

Timepoint

45 minute after intervention (15 minute after injection)

Method of measurement

visual analog scale

Secondary outcomes

1

Description

Analgesia during access cavity preparation and entrance into the root canal

Timepoint

during access cavity preparation and entrance into the pulp chamber

Method of measurement

visual analog scale

Intervention groups

1

Description

Control2 intervention group one Capsule Dexamethasone 0.5 mg(Aburaihan Pharmaceutical Co, Iran) 30 min before injection Intervention category treatment

Category

Treatment - Drugs

2

Description

Control3 control group one Capsule (placebo: Lactose) 30 min before injection

Category

Placebo

3

Description

intervention groups one Capsule pharmapain 400 mg(Pharma chemie Pharmaceutical Co , Iran) 30 min before injection

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of Endodontics, Faculty of Dentistry, Tabriz University of Medical Sciences.

Full name of responsible person

Dr. Negar Moghaddam

Street address

Department of Endodontics, Faculty of Dentistry, Tabriz University of Medical Science, Golgasht Street, Tabriz, East Azerbaijan, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research ,Tabriz University of Medical Science

Full name of responsible person

Dr. Mohammadreza Rashidi

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International Relations Office, No 2 Central Building, Tabriz University of Medical Sciences, Golgasht Street, Tabriz, East Azerbaijan, Iran

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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 ,Tabriz University of Medical Science

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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Science

Full name of responsible person

Dr. Negar Moghaddam

Position

DDS/ Assistant Professor of Endodontics

Other areas of specialty/work

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Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tabriz University of Medical Science

Full name of responsible person

Dr. Negar Moghaddam

Position

DDS/ Assistant Professor of Endodontics

Other areas of specialty/work

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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