Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 of 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 as have 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
Street address
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
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Person responsible for updating data

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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