

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

The effect of Amitriptyline and Imipramyne on pain reduction in teeth with irreversible pulpitis while preparing access cavity.

Protocol summary

Summary

The purpose of this study is to evaluate the effect of Amitriptyline and Imipramyne on pain reduction in teeth with symptomatic irreversible pulpitis while preparing access cavity. The patients must have a molar tooth with a pulpal and periapical diagnosis of symptomatic irreversible pulpitis; must be healthy , must not have any systemic disease, must not use any medicaments; must not have any allergy to the drugs used in this experiment; must not use tricycle antidepressant and after the administration of local anesthetic (lidocaine 2% + 1/100000 epinephrine) must still experience pain during the preparation of the access cavity. 66 16 to 60 year old patients with these criteria will be evaluated. After getting a informed consent, the level of pain experienced by the patients during access cavity preparation will be assessed by a McGill Visual Analog Scale then the patients will be randomly divided into three groups : 1. administration of 0.2 ml Amitriptyline 1mg/ml 2- administration of 0.2ml Imipramyne 1mg/ml 3- control group (administration of 0.2ml propylene glycol) and 5 minutes after the application of the drugs the degree of pain experienced will be assessed again. The primary expected outcome is decreased pain during access cavity preparation. The study will be a double-blind study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201110317963N1**

Registration date: **2012-04-01, 1391/01/13**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-04-01, 1391/01/13

Registrant information

Name

Mohsen Aminsobhani

Name of organization / entity

Tehran University of Medical Sciences, Faculty Of Dentistry

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Recruitment status

Recruitment complete

Funding source

Research Center of Tehran University of Medical Sciences

Expected recruitment start date

2012-04-01, 1391/01/13

Expected recruitment end date

2013-03-20, 1391/12/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Amitriptyline and Imipramyne on pain reduction in teeth with irreversible pulpitis while preparing access cavity.

Public title

The local effect of two antidepressant drugs on pain reduction in teeth with severe tooth ache (irreversible tooth pulp inflammation) during root canal therapy.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patient (male or female)with a molar tooth with a pulpal and periapical diagnosis of symptomatic irreversible pulpitis; healthy patient with a non-contributory medical history; patient must not use any medicaments; must not have any allergy to the drugs used in this experiment or other tricyclic antidepressant; must not use tricyclic antidepressant; after administration of local anesthetic must still experience pain during the preparation of the access cavity. exclusion criteria: patient (male or female) with any systemic disease; patient using any medicament; patient with allergy to the drugs used in this experiment or other tricyclic antidepressant; use of tricyclic antidepressant; after administration of local anesthetic does experience pain during the preparation of the access cavity.

Age

From **16 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **66**

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

Tehran University of Medical Sciences

Street address

Ghods st, Keshavarz Boulevard

City

Tehran

Postal code

1417653761

Approval date

2011-03-15, 1389/12/24

Ethics committee reference number

90-04-69-15772-49211

Health conditions studied

1

Description of health condition studied

Irreversible pulpitis

ICD-10 code

K04.0

ICD-10 code description

Diseases of pulp and periapical tissues-Pulpitis-irreversible

Primary outcomes

1

Description

pain

Timepoint

5 minute after application of the drug

Method of measurement

VAS scale

Secondary outcomes

empty

Intervention groups

1

Description

0.2 ml Amitriptyline + propylen glycole (1mg/ml) is applied locally on the carious dentin of the tooth and after 5 minutes its effect on the patients pain is assessed

Category

Treatment - Drugs

2

Description

0.2 ml Imipramine + propylen glycole (1mg/ml) is applied locally on the carious dentin of the tooth and after 5 minutes its effect on the patients pain is assessed

Category

Treatment - Drugs

3

Description

0.2 ml propylen glycole is applied locally on the carious dentin of the tooth and after 5 minutes its placebo effect on the patients pain is assessed

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Dental Faculty of Tehran University of Medical Sciences

Full name of responsible person

Street address

Dental Faculty of Tehran University of Medical Sciences , North Kargar st

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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Street address

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Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Research Center of Tehran 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

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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