# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

31 May 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
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Tehran University of Medical Sciences, Faculty Of Dentistry
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Iran (Islamic Republic of)
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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 Bulevard

**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 applyed 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 Imipramyne + propylen glycole ( 1mg/ml) is applyed 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 applyed 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**

Tehran

## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**

Research Center of Tehran University of Medical Sciences

**Full name of responsible person**

Mohsen Aminsobhani

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Research Center of Tehran University of Medical Sciences, Ghods st, Keshavarz Bulevard

**City**

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**

Dental Faculty of Tehran University of Medical Sciences

**Full name of responsible person**

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**Position**

Assistant Professor, Endodontist

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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*