

# The effect of clonidine as an adjunct to lidocaine on postoperative pain control following root canal treatment

<b>Submission date</b> 10/12/2016	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 29/12/2016	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 19/01/2023	<b>Condition category</b> Oral Health	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Root canal treatment is a common dental procedure used to treat an infection at the centre of a tooth in an area called the root canal system. The infection can be extremely painful, and the only way of treating it is to remove the bacteria from the root canal system (root canal treatment) or to remove the tooth. Root canal treatment is generally considered to be an extremely painful procedure, and so modern research into root canal treatment generally focusses on decreasing the pain for patients who may already be nervous of the treatment. The aim of this study is to investigate the pain relieving qualities of a new combination of clonidine (an anti-anxiety medication used in general surgery) with 2% lidocaine (the typical numbing medication used in the dental office) compared to normal treatment.

### Who can participate?

Adults who require root canal treatment.

### What does the study involve?

Participants are randomly allocated to one of two groups who each receive a different numbing treatment before having their root canal surgery. Those in the first group receive an injection into the gum (inferior alveolar nerve block) to numb the mouth using lidocaine (a local anaesthetic used by dentists) with epinephrine (adrenaline), which is the usual solution used for this procedure. Those in the second group receive the injection with the new solution made up of clonidine (an anti-anxiety medication used in general surgeries) and lidocaine. In both groups, their level of pain is assessed using a scale before the injection and then 6, 12, 24, 36, 48, and 72 hours afterwards.

### What are the possible benefits and risks of participating?

The benefits to the patient include receiving a root canal performed by a root canal specialist. The risks involved are minimal as the patient requires the root canal to remove the dental pain and infection, and the novel anesthetic (clonidine + 2% lidocaine) has been proven to be safe in other studies.

Where is the study run from?  
Isfahan University of Medical Sciences (Iran)

When is the study starting and how long is it expected to run for?  
September 2014 to January 2016

Who is funding the study?  
Isfahan University of Medical Sciences (Iran)

Who is the main contact?  
Professor Elham Shadmehr  
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## Contact information

**Type(s)**  
Scientific

**Contact name**  
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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
142287

## Study information

**Scientific Title**  
The effect of clonidine as an adjunct to lidocaine on postoperative pain control following root canal treatment: a prospective randomized double-blind study

**Study objectives**

Addition of clonidine to 2% lidocaine will reduce postoperative pain after root canal treatment.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Isfahan University of Medical Sciences, 14/04/2014, ref: 142287

**Study design**

Randomized controlled double-blind clinical trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Other

**Study type(s)**

Treatment

**Participant information sheet**

Not available in web format, please use contact details to request a participant information sheet

**Health condition(s) or problem(s) studied**

Postoperative pain after root canal treatment

**Interventions**

Patients are randomised to one of two groups.

Group 1: Patients receive 1.8 mL of 2% lidocaine with clonidine (15 µg/mL) using a conventional inferior alveolar nerve block (IANB).

Group 2: Patients receive 1.8 mL of 2% lidocaine with epinephrine (1:80,000) using a conventional inferior alveolar nerve block (IANB).

All treatments are completed in a single-visit appointment. Pain scores are recorded preoperatively and at 6, 12, 24, 36, 48, and 72 hours after endodontic treatment using a Heft-Parker visual analog scale (VAS). Also, the total number of tablets of analgesics consumed by the patient are also recorded and analyzed by chi-squared, paired t-test and repeated measure of ANOVA ( $p < 0.05$ ).

**Intervention Type**

Drug

**Phase**

Not Applicable

**Drug/device/biological/vaccine name(s)**

Clonidine, lidocaine

**Primary outcome measure**

1. Pain scores, recorded using a Heft-Parker visual analog scale (VAS) preoperatively and at 6, 12, 24, 36, 48, and 72 hours after endodontic treatment
2. Number of pain medications consumed are recorded continuously for 72 hours postoperatively

**Secondary outcome measures**

Duration of postoperative pain is assessed using a visual analog scale (VAS) preoperatively and at 6, 12, 24, 36, 48, and 72 hours

**Overall study start date**

15/09/2014

**Completion date**

15/01/2016

**Eligibility****Key inclusion criteria**

1. Adult patients (18 years of age or older)
2. In good medical condition (American Society of Anesthesiologists classification 1)
3. Diagnosed with symptomatic irreversible pulpitis and normal/symptomatic apical periodontitis at the mandibular first or second molars

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

100

**Total final enrolment**

100

**Key exclusion criteria**

1. Patients with active signs of oral infections or inflammation
2. History of addiction or use of  $\beta$  blockers
3. Patients taking any medications that could affect anesthetic assessment (analgesics or opioids at least one week before treatments)

4. Patients with allergies or contraindications to the use of clonidine, epinephrine or ibuprofen
5. Female patients who were pregnant or breastfeeding
6. Patients with no response to cold testing
7. Perirapical pathosis (other than a widened periodontal ligament)
8. No vital coronal pulp tissue upon access cavity preparation (partial necrosis)

**Date of first enrolment**

15/11/2014

**Date of final enrolment**

15/01/2016

## Locations

**Countries of recruitment**

Iran

**Study participating centre**

Isfahan University of Medical Sciences

Hezar Jarib Street

Isfahan

Iran

8168913673

## Sponsor information

**Organisation**

Isfahan University of Medical Sciences

**Sponsor details**

Hezar Jarib Street

Isfahan

Iran

8168913673

**Sponsor type**

University/education

**Website**

dnt.mui.ac.ir

**ROR**

<https://ror.org/04waqzz56>

# Funder(s)

## Funder type

University/education

## Funder Name

Isfahan University of Medical Sciences

## Alternative Name(s)

, IUMS

## Funding Body Type

Government organisation

## Funding Body Subtype

Local government

## Location

Iran

# Results and Publications

## Publication and dissemination plan

Planned publication in the Journal of Dental Research.

## Intention to publish date

31/07/2019

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Elham Shadmehr (Eshadmehr@buffalo.edu)

## IPD sharing plan summary

Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		05/07/2021	19/01/2023	Yes	No