ISRCTN70419178 https://doi.org/10.1186/ISRCTN70419178

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

Submission date
10/12/2016

Recruitment status
No longer recruiting

Registration date
29/12/2016

Overall study status
Completed

Last Edited
19/01/2023

Condition category
Oral Health

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
elham.shadmehr@gmail.com

Contact information

Type(s)
Scientific

Contact name
Prof Elham Shadmehr

ORCID ID
http://orcid.org/0000-0003-3985-6570

Contact details
University of California
707 Parnassus ave, D3214
San Francisco
United States of America
94143
-
elham.shadmehr@gmail.com

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 ß 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?
Results article		05/07/2021	19/01/2023	Yes	No