

Effectiveness of anesthesia in dental patients undergoing root canal treatment

Submission date 02/02/2021	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 23/02/2021	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 23/02/2021	Condition category Oral Health	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

In mandibular back teeth when tissues are damaged it may result in a severely painful condition which is characterized by the presence of inflammation. Root canal treatment is a standard required procedure that is performed to eliminate the diseased condition in such teeth.

Effective anesthesia is required to perform this procedure.

The aim of the study is to compare the effectiveness of two types of anesthesia to make the lower inflamed back teeth numb properly to complete the root canal treatment without pain.

Who can participate?

Adult patients presenting with pain because of irreversibly damaged pulpal tissues in their mandibular back teeth will participate in this study.

What does the study involve?

The study involves the injection of two types of anesthesia to compare their effectiveness.

What are the possible benefits and risks of participating?

None

Where is the study run from?

Qassim University (Saudi Arabia)

When is the study starting and how long is it expected to run for?

December 2019 to February 2023

Who is funding the study?

Investigator initiated and funded

Who is the main contact?

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Contact information

Type(s)

Public

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Protocol serial number

Nil known

Study information

Scientific Title

Efficacy of 4% articaine versus 2% lidocaine as supplemental infiltration for mandibular molars with irreversible pulpitis

Study objectives

There is a difference between the efficacy of 4% articaine and 2% lidocaine for supplemental buccal infiltration in mandibular molars with Irreversible pulpitis after a failed inferior alveolar nerve block.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 10/12/2019, Dental Ethics Committee of Alrass Dental College of Qassim University of Saudi Arabia (Alrass Dental College, 11 King Abdulaziz Street, Al Rass, Saudi Arabia; +966 163800050 Ext. 10685; rass.ethical@qudent.org), ref: DRC/13M/4-20

Study design

Interventional randomized controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Control of pain in symptomatic patients undergoing root canal treatment for mandibular molars with irreversible pulpitis

Interventions

We shall divide the patients into two groups after a standard inferior alveolar nerve block (IANB) anesthesia fails, one group will receive 2% Lidocaine buccal infiltration and the other group will receive 4% Articaine by a blinded operator.

Masking will be done by covering the anesthesia cartridges using aluminium foils. The assignment will be done using computer generated numbers. At none of these levels, the principal investigator will be involved. This will eliminate operator related bias.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

4% articaine, 2% lidocaine with 1:100000 epinephrine

Primary outcome(s)

Pain measured using a visual analogue scale (VAS) after 5 minutes of anesthesia

Key secondary outcome(s)

There are no secondary outcome measures

Completion date

01/02/2023

Eligibility**Key inclusion criteria**

Symptomatic adult patients having mandibular first and/ or second molar tooth diagnosed with acute irreversible pulpitis.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Patients taking antibiotic
2. Medically compromised
3. Effective inferior alveolar nerve block
4. Patients with immature root apex
5. Non-restorable teeth
6. Patient refused to sign the inform consent
7. Pregnant patient
8. Patient with history of allergy from any of the contents of anesthesia

Date of first enrolment

17/01/2021

Date of final enrolment

01/02/2023

Locations

Countries of recruitment

Saudi Arabia

Study participating centre

Qassim University

College of dentistry

Al Rass

Saudi Arabia

52719

Sponsor information

Organisation

Qassim University

ROR

<https://ror.org/01wsfe280>

Funder(s)

Funder type

Other

Funder Name

investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

All data generated or analysed during this study will be included in the subsequent results publication

IPD sharing plan summary

Other