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Effectiveness of anesthesia in dental patients undergoing root canal treatment

Submission date
02/02/2021

Recruitment status
No longer recruiting

Registration date
23/02/2021

Overall study status
Completed

Last Edited
23/02/2021

Condition category
Oral Health

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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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Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet.

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

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
10/12/2019

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

Age group
Adult

Sex
Both

Target number of participants
50

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
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Sponsor information

Organisation
Qassim University

Sponsor details
Al Rass Dental College
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Sponsor type
University/education

Website
http://www.qu.edu.sa/Pages/Home.aspx

ROR
https://ror.org/01wsfe280

Funder(s)

Funder type
Other

Funder Name
investigator initiated and funded

Results and Publications

Publication and dissemination plan

The results of this study will be disseminated by submitting in relevant dentistry journal and by presentations at local and international scientific conferences.

Intention to publish date
01/02/2024

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