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Dental sensitivity after applying cold saline water during endodontic treatment

Submission date
05/08/2022

Recruitment status
No longer recruiting

Registration date
28/09/2022

Overall study status
Completed

Last Edited
09/10/2024

Condition category
Oral Health

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Dental pain is frequent after root canal treatment, which can turn into a stressful situation for both the patient and the dentist. Anti-inflammatory drugs or analgesics are usually indicated to help reduce pain after root canal treatment. However, despite being relatively safe drugs, they could cause gastrointestinal intolerance, kidney, liver or respiratory damage. As a local treatment option, free of pharmacological side effects, a new irrigation protocol known as cryotherapy has emerged, which is based on applying cold saline water inside the root canal in order to reduce this postoperative pain. The aim of this study is to evaluate tooth sensitivity after applying cryotherapy during endodontic treatment.

Who can participate?
Patients with a diagnosis of pulp necrosis in teeth with one or two roots

What does the study involve?
Participants are randomly allocated to be treated with or without foraminal enlargement and with or without cryotherapy.

What are the possible benefits and risks of participating?
The risks are common to every root canal treatment performed, which are: risk of instrument fractures (instrument breakage), root perforation, the liquid (chemical substance) used to wash the tooth canal can leak to other tissues and cause irritation, and there may be post-treatment pain and swelling. These are the main risks while performing root canal treatment. It is worth remembering that failure to perform root canal treatment can lead to tooth loss as an infection and inflammation can occur. This study can provide the following benefits: reduction of factors that lead to increased pain after root canal treatment with an updated technique.

Where is the study run from?
Pontifícia Universidade Católica do Paraná (Brazil)

When is the study starting and how long is it expected to run for?
October 2021 to July 2023

Who is funding the study?
1. Pontifícia Universidade Católica do Paraná (Brazil)
2. Conselho Nacional de Desenvolvimento Científico e Tecnológico (CNPq) (Brazil)

Who is the main contact?
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Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
1

Study information

Scientific Title
Evaluation of cryotherapy and its effect on postoperative pain relief in single and bi-radicular teeth treated endodontically with and without foraminal enlargement

Acronym
EICPPR

Study objectives
Cryotherapy may be a therapeutic option to improve the postoperative phase on patients after canal treatment with and without foraminal enlargement.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 07/10/2021, Comitê de Ética e Pesquisa Pontifícia Universidade Católica do Paraná (R. Imac. Conceição, 1155 - Prado Velho, Curitiba - PR, 80215-901 Brazil; +55 (41)3271 2103; nep@pucpr.br), ref: 5.024.031

Study design
Single-centre randomized controlled 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 the contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Single and bi-radicular teeth diagnosed with pulpal necrosis

Interventions

After applying the inclusion criteria, teeth will be selected and treated, which will be distributed into eight groups.
1. HIV-negative patients treated without foraminal enlargement
2. HIV-negative patients treated with foraminal enlargement
3. HIV-negative patients treated without foraminal enlargement and with cryotherapy
4. HIV-negative patients treated with foraminal enlargement and cryotherapy
5. HIV-positive patients treated without foraminal enlargement
6. HIV-positive patients treated with foraminal enlargement
7. HIV-positive patients treated without foraminal enlargement and with cryotherapy
8. HIV-positive patients treated with foraminal enlargement and cryotherapy

The treatments will be performed in a single session following four different protocols which will be chosen randomly for each case. Patients will be anaesthetized using 1.8 ml of 2% mepivacaine with 1:100,000 epinephrine. The teeth will be isolated and the opening of the pulp chamber will be done using a spherical diamond bur in high speed. After finding the pulp chamber, a truncated conical drill will be used to eliminate the remains of the ceiling and refine the walls of the pulp chamber. With the aid of a type K #10 instrument, the channels will be explored and located. Establishing the working length (CT) will be done using an electronic apex locator, Root ZX II (J Morita), and a K-type instrument of the most appropriate diameter for the canal anatomy. The CT will be set 1 mm short of the 0.0 mark on the locator display.
Root canal preparation will be performed using a Reciproc R50 (50.05) instrument mounted on a Smart plus motor (Dentsply). The canals will be irrigated with 15ml of 2.5% sodium hypochlorite. Debris on the instrument will be removed using gauze soaked in 70% alcohol after every three pecking movements. In the groups where foraminal enlargement will be performed, a K file #40. 02 will be used up to the 0.0 mark on the electronic apical locator display, corresponding to the apical foramen of the tooth.

For the groups where cryotherapy will be performed, a final irrigation will be performed using 20 ml of saline solution previously cooled to a temperature of 2 degrees centigrade. The syringe with the serum will be previously prepared by leaving it 2 days before in a refrigerator calibrated to maintain a temperature between 1 and 2 degrees centigrade. The temperature confirmation will be carried out with the aid of a digital thermometer. The syringe will be transported from the refrigerator to the clinical room 5 minutes in advance, before starting the final irrigation. The syringe will be transported in a thermal box with ice and with the digital thermometer to check that the temperature of the box remains between 1 and 2 degrees centigrade. To ensure that the serum reaches the apical region, the “EndoVac” (Kerr) irrigation system will be used, which fulfills a negative irrigation principle. A cannula (MICRO) of the EndoVac will be inserted up to the working length and then the application of the serum will begin. Irrigation will be timed to be carried out within a maximum period of 5 minutes to avoid variations in temperature. Subsequently, the canals will be dried using sterile paper points.

In all cases, filling will be performed with AH PLUS (Dentsply) endodontic cement and calibrated gutta-percha cones, using Shielder's lateral condensation technique. Gutta-percha cones will be cut with a heated instrument at the cemento-enamel junction.

Intervention Type

Procedure/Surgery

Primary outcome measure

Pain intensity will be evaluated using a visual analogue scale (VAS), considered valid and reliable, from 0 to 10, where 0, 1–2, 3–7 and 8–10 means complete absence of pain, mild pain, moderate pain. and severe pain, respectively. Prior to the induction of local anesthesia, patients will be asked to record preoperative pain on the VAS to confirm the complete absence of pain. Postoperative pain was verified at 6, 12, 24, 48 and 72 hours and 7 days after endodontic treatment.

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
06/10/2021

Completion date
30/06/2023

Eligibility

Key inclusion criteria
Only single or biradicular teeth with a negative response to vitality tests will be considered, but with a diagnosis of pulp necrosis, with or without the presence of images suggestive of periapical lesions.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
180

Key exclusion criteria
1. Patients with acute apical pain
2. Pregnant patients
3. Patients with continuous use of corticosteroids, analgesics or antibiotics
4. Teeth with previous root canal treatment
5. Vital teeth
6. Anatomical foramen with a larger diameter with a type K #20 instrument or smaller with a type K #10 instrument
7. Teeth with root resorption that compromises the apical region

Date of first enrolment
01/06/2022

Date of final enrolment

01/09/2022

Locations

Countries of recruitment
Brazil

Study participating centre
PUCPR - Pontifícia Universidade Católica do Paraná Dental Clinic
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Sponsor information

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University/education

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Funder(s)

Funder type
University/education

Funder Name
Pontificia Universidade Católica do Paraná

Alternative Name(s)
Pontifical Catholic University of Paraná, PUCPR

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Brazil

Funder Name
Conselho Nacional de Desenvolvimento Científico e Tecnológico

Alternative Name(s)
Brazilian National Council for Research and Development, National Council for Scientific and Technological Development, CNPq

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Brazil

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
30/09/2023

Individual participant data (IPD) sharing plan
Current IPD sharing statement as of 23/06/2023:
The datasets generated and/or analysed during the current study will be published as a supplement to the results publication

Previous IPD sharing statement:
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary

Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		28/08/2024	09/10/2024	Yes	No