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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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# Contact information

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Scientific


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# Additional identifiers

### Clinical Trials Information System (CTIS)
Nil known

### ClinicalTrials.gov (NCT)

Nil known

### Protocol serial number
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

### Study type(s)
Treatment

### 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(s)
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.

## Key secondary outcome(s))
There are no secondary outcome measures

## 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

### Healthy volunteers allowed
No

### Age group
Adult

### Sex
All

### 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

**Organisation**
Pontifícia Universidade Católica do Paraná

**ROR**
https://ror.org/02x1vjk79

# 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 - Conselho Nacional de Desenvolvimento Científico e Tecnológico, National Council for Scientific and Technological Development (Conselho Nacional de Desenvolvimento Científico e Tecnológico), CNPq

**Funding Body Type**
Government organisation

**Funding Body Subtype**
National government

### Location
Brazil

# Results and Publications

### 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 |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |