

# Evaluation of the pain level of patients submitted to endodontic treatment with varying techniques, in order to identify the one that causes less pain

<b>Submission date</b> 15/06/2019	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 28/06/2019	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 04/07/2024	<b>Condition category</b> Oral Health	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

The knowledge of the mechanisms responsible for triggering the painful response in endodontics (treatment of tooth pulp) is essential to perform accurate procedures, avoiding the possible causes of pain. This study determined the pain levels of patients submitted to endodontic treatment, with or without the apical foramen enlargement, using chorexidine or sodium hypochlorite with and without agitation with XP- endo Finisher.

### Who can participate?

Patients aged over 18 years, requiring endodontic treatment at the trial centre.

### What does the study involve?

Participants will undergo endodontic treatment using one of seven similar methods. Following treatment, pain level will be assessed to determine which method produces the least pain.

### What are the possible benefits and risks of participating?

**Benefits:** Participants will receive the necessary care free of charge and with high-quality materials and equipment. This treatment will improve oral health and restore the function of the affected tooth.

**Risks:** instrument fractures (breakage of instrument), root perforation, extravasation of the chemical used causing irritation of affected tissues, post-treatment pain and swelling. These are the main risks during the treatment of the canal

### Where is the study run from?

Pontifical Catholic University of Paraná, Brasil

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

February to May 2019

Who is funding the study?  
Pontifical Catholic University of Paraná

Who is the main contact?  
Prof. Leonardo Alexandre Fernandes  
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## Contact information

**Type(s)**  
Scientific

**Contact name**  
Prof Leonardo Alexandre Fernandes

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## Additional identifiers

**EudraCT/CTIS number**  
Nil known

**IRAS number**

**ClinicalTrials.gov number**  
Nil known

**Secondary identifying numbers**  
3056118

## Study information

**Scientific Title**  
Endodontic post-treatment pain level with variation of foraminal enlargement and irrigation solution with and without agitation with XP-endo Finisher: a randomized clinical trial

**Study objectives**  
The technique that uses sodium hypochlorite, being more irritating causes more pain in the postoperative endodontic

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

Approved 04/12/2018, Pontifical Catholic University of Paraná (Rua Imaculada Conceição 1155, Prado Velho, Curitiba, Brasil; +55 41 3271-2103; nep@pucpr.br), ref: 3056118

## **Study design**

Double-blind 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 patient information sheet

## **Health condition(s) or problem(s) studied**

Caries with pulp exposure

## **Interventions**

Current interventions as of 27/04/2021:

In this double-blind randomized clinical trial, participants were divided into 7 groups: SH2.5 (2.5% sodium hypochlorite) (n = 30), CHX2.0 (chlorhexidine 2.0%) (n = 30), CHX2,0EF (chlorhexidine 2.0% with foraminal enlargement) (SH = 0.5), SH2,5EF (sodium hypochlorite 2.5% with foraminal enlargement) (SH) and SH2,5XPF (sodium hypochlorite 2 (5% agitated with XP-endo Finisher) (n = 20), SH2,5XPF-EF (2.5% sodium hypochlorite agitated with XP-endo Finisher and with foraminal enlargement) (n = 15) and SH2,5PC sodium hypochlorite 2.5% after orofacial cancer) (n = 15). The teeth were instrumented with the Wave One Gold Medium file, filled with AH Plus cement and the closed cavity with cotosol. Randomisation was done to eliminate bias and to equalize the distribution of patients in the groups using the Excel computer program with a random list of numbers from 1 to 7. In case the same patient had more than one element to be treated, the tooth located in the upper right hemi-arch was the first, followed by hemi-upper left arch, lower right and lower left, respecting the minimum limit of 10 days and absence of pain between the treatment of one tooth and another. Only the operator who performed the treatment knew which technique was being used.

Endodontic treatments were performed by a single operator specialized in endodontics. After the clinical examination, the cold test (Endo-frost; Coltene-Whaledent, Langenau, Germany) was used to determine the vitality of the pulp followed by the presence or absence of bleeding of

the root canals during the preparation of endodontic access. If there was no painful response after 5 seconds of applying a cotton ball and not bleeding, the teeth were classified as necrotic. The treatment was performed in all patients in a single visit.

The groups CHX2.0 (chlorhexidine 2.0%), CHX2.0EF (chlorhexidine 2.0% with foraminal increase) and SH2.5PC sodium hypochlorite 2.5% after orofacial cancer) will be excluded before data collection started, as there are no recommendations for the use of chlorhexidine with XP-endo Finisher. The study team will follow the XP-endo finisher manufacturing manual (FKG Dentaire) and the literature data. The chlorhexidine group will be excluded before data collection, since the literature makes it clear that there is no difference between sodium hypochlorite and chlorhexidine when evaluating postoperative endodontic pain (Zarei and Bidar 2006, 2006; Almeida et al., 2012). Groups of cancer patients will also be excluded because most were using painkillers that interfered with the measurement of VAS.

#### **Previous interventions:**

In this double-blind randomized clinical trial, participants were divided into 7 groups: SH2.5 (2.5% sodium hypochlorite) (n = 30), CHX2.0 (chlorhexidine 2.0%) (n = 30), CHX2.0EF (chlorhexidine 2.0% with foraminal enlargement) (SH = 0.5), SH2.5EF (sodium hypochlorite 2.5% with foraminal enlargement) (SH) and SH2.5XPF (sodium hypochlorite 2 (5% agitated with XP-endo Finisher) (n = 20), SH2.5XPF-EF (2.5% sodium hypochlorite agitated with XP-endo Finisher and with foraminal enlargement) (n = 15) and SH2.5PC sodium hypochlorite 2.5% after orofacial cancer) (n = 15). The teeth were instrumented with the Wave One Gold Medium file, filled with AH Plus cement and the closed cavity with cotosol. Randomisation was done to eliminate bias and to equalize the distribution of patients in the groups using the Excel computer program with a random list of numbers from 1 to 7. In case the same patient had more than one element to be treated, the tooth located in the upper right hemi-arch was the first, followed by hemi-upper left arch, lower right and lower left, respecting the minimum limit of 10 days and absence of pain between the treatment of one tooth and another. Only the operator who performed the treatment knew which technique was being used.

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#### **Intervention Type**

Procedure/Surgery

#### **Primary outcome measure**

Pain measured by a visual analogue scale, 6, 12, 24, 72 hours and 7 days after completion of treatment

#### **Secondary outcome measures**

Use of antidepressants and previous treatment of radiotherapy head and neck from patient records.

#### **Overall study start date**

28/03/2018

**Completion date**

31/05/2019

## Eligibility

**Key inclusion criteria**

1. Older than 18 years
2. Need endodontic treatment
3. Negative response to vitality tests
4. The included teeth were monoradical and biradical, superior and inferior, with or without image suggestive of periapical lesion

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

170

**Total final enrolment**

170

**Key exclusion criteria**

1. Acute apical pain and/or abscess
2. Endodontic retreatment
3. Pregnant women on antibiotics, corticosteroids or analgesics
4. Complications from systemic diseases
5. Anatomic diameter greater than the K-type file 20 mm or less than the K-type file 10, in addition to teeth with resorption and open apex

**Date of first enrolment**

18/02/2019

**Date of final enrolment**

28/05/2019

## Locations

**Countries of recruitment**

Brazil

**Study participating centre**  
**Pontifical Catholic University of Paraná**  
R. Imac. Conceição, 1155  
Prado Velho  
Curitiba  
Brazil  
80215-901

## **Sponsor information**

### **Organisation**

Pontifical Catholic University of Paraná

### **Sponsor details**

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### **Sponsor type**

University/education

### **Website**

<https://www.pucpr.br>

### **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

## **Results and Publications**

### **Publication and dissemination plan**

Planned publication in a high-impact peer-reviewed journal

### **Intention to publish date**

30/06/2021

### **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

### **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>			04/07/2024	Yes	No