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

Submission date
15/06/2019

Recruitment status
No longer recruiting

Registration date
28/06/2019

Overall study status
Completed

Last Edited
04/07/2024

Condition category
Oral Health

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

Plain English summary of protocol

Background and study aims
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?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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

Study type(s)
Treatment

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

Key secondary outcome(s))
Use of antidepressants and previous treatment of radiotherapy head and neck from patient records.

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 monoradicadic and biradicculated, superior and inferior, with or without image suggestive of periapical lesion

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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
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Sponsor information

Organisation
Pontifical Catholic University of 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

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article			04/07/2024	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes