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Outcome of traumatized teeth treated with laser therapy

Submission date
26/04/2023

Recruitment status
No longer recruiting

Registration date
27/06/2023

Overall study status
Completed

Last Edited
27/06/2023

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
This research aims to examine how well a specific dental treatment works for injured teeth with dead pulp. The treatment, called Regenerative Endodontic Procedure (REP), involves cleaning and filling the root canal with a blood clot to encourage the growth of new healthy tissue. The study will use Photodynamic Therapy (PDT) and Photobiomodulation (PBM) to help disinfect the area and promote cell growth. The researchers will measure the success of the treatment by looking at the size of the foramen (opening at the end of the tooth root), the healing of the surrounding tissues, and the shape of the tooth root. Overall, the goal is to improve the healing process for these types of injuries.

Who can participate?
Patients between the ages of 8 and 14 years with one or more immature permanent teeth had suffered dental trauma and consequently pulp necrosis,
and complete medical records.

What does the study involve?
In this retrospective study, data was collected from patient records with immature traumatized and necrotic permanent teeth.
The sample was divided into 2 groups: Group A with 12 treatments using laser therapy in the form of PDT and PBM, and Group B with 12 teeth that did not receive any laser therapy.

What are the possible benefits and risks of participating?
The benefits of participating include fewer treatment sessions, resulting in less stress for the pediatric patient. The objective of the regeneration treatment itself is to restore root formation and repair the periapical lesion.

The risks include potential root fractures and inadequate reduction of the periapical lesion.

Where is the study run from?
Department of Endodontics, Pontific Catholic University of Curitiba, Paraná (Brazil)

When is the study starting and how long is it expected to run for?
September 2016 to December 2024

Who is funding the study?
Department of Endodontics, Pontific Catholic University of Curitiba, Paraná (Brazil)

Who is the main contact?
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Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
PUCPR 2017-2023

Study information

Scientific Title
Radiographic evaluation of traumatized immature teeth treated with regenerative endodontics and laser therapy

Study objectives

Clinical outcomes of imature permanent teeth have root development enhanced by rep treatment associated to PDT and PBM (laser therapies).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 17/12/2017, CONEP (SEPN 510 Norte, Block A, 3rd Floor, Ex-INAN Building - Unit II - Ministry of Health, Brasilia, Brazil; +55 61 3315-5878; conep@saude.gov.br), ref: 2.512356

Study design
Single-centre interventional randomized parallel

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
University/medical school/dental school

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Necrotic immature teeth due to dental trauma

Interventions
Data was collected from patient records with immature traumatized and necrotic permanent teeth treated at the Traumatology discipline, Department of Endodontics, Pontific Catholic University of Curitiba, Paraná, Brazil. The sample consisted of 24 permanent teeth with immature root canals and periapical lesions from patients between 8 and 14 years old. All teeth were treated by a single operator. The teeth were divided into 2 groups: Group A with 12 treatments using laser therapy in the form of photodynamic therapy (PDT) and photobiomodulation therapy (PBM), and Group B with 12 teeth that did not receive any laser therapy. The preoperative exams for the study included digital periapical radiographs to confirm the presence of an infected tooth with incomplete root development and an apical foramen diameter greater than 1.0 mm. Digital periapical radiographs were taken immediately after the procedure (June/July 2021), as well as at 6, 12, and 18 months postoperatively.

Randomisation
The groups were divided based on the application of bioactive endodontic cement on the blood clot. The random sequence for material selection was performed by each patient, who blindly drew the material for cervical sealing. Patients with two selected teeth for the research randomly determined which tooth would be treated first and which material would be applied. The material used for each tooth was kept confidential from the evaluators, using a case-associated number. Along with the blinding of material selection, this study is double-blind for

both the patients and the examiners of the response variables. The allocation secrecy involved sealing the material selection in an opaque envelope with a corresponding number, without the patient identifying the material based on the number. The allocation sequence was generated by the Discipline of Integrated Clinical Dentistry in Dentoalveolar Traumatology at the Dentistry course of Pontifical Catholic University of Paraná, based on the order of patient arrival, and the treatments were performed by a single Endodontics specialist.

Intervention Type
Procedure/Surgery

Primary outcome measure
Apical root closure and root development will be measured using the software Image J (versão 1.52; National 17 Institutes of Health, Bethesda, MD) with “Turbo Reg” (Biomedical Imaging Group, Swiss Federal Institute of Technology, Lausanne, VD, Suíça) at 0, 6, 12 and 18 months

Secondary outcome measures
Chen et al 2012 scale of root end outcomes measured by image assessment at 18 months

Overall study start date
02/09/2016

Completion date
10/12/2024

Eligibility

Key inclusion criteria
1. Between the ages of 8 and 14 years
2. One or more immature permanent teeth had suffered dental trauma and consequently pulp necrosis
3. Complete medical records, including digital periapical radiographs

Participant type(s)
Patient

Age group
Child

Lower age limit
8 Years

Upper age limit
14 Years

Sex
Both

Target number of participants
The sample consisted of 24 permanent teeth with immature root canals and periapical lesions

Total final enrolment
25

Key exclusion criteria
1. Vital teeth or teeth with complete root formation
2. Vertical fractures of any size
3. Patients with low treatment compliance

Date of first enrolment
02/09/2017

Date of final enrolment
30/09/2023

Locations

Countries of recruitment
Brazil

Study participating centre
Traumatology discipline, Department of Endodontics, Pontific Catholic University of Curitiba
1155, Imaculada Conceição street, Prado Velho.
Curitiba
Brazil
80215-901

Sponsor information

Organisation
Pontifícia Universidade Católica do Paraná

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Sponsor type
University/education

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http://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
21/11/2024

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
Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			30/05/2023	No	Yes