

# Outcome of traumatized teeth treated with laser therapy

<b>Submission date</b> 26/04/2023	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 27/06/2023	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 27/06/2023	<b>Condition category</b> Oral Health	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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?  
vania.westphalen@pucpr.br

## Contact information

**Type(s)**  
Principal investigator

**Contact name**  
Prof Vânia Westphalen

**ORCID ID**  
<https://orcid.org/0000-0003-2313-7117>

**Contact details**  
Rua Pasteur, 486/401  
Curitiba  
Brazil  
80250-080  
+55 41999625110  
vania.westphalen@pucpr.br

## Additional identifiers

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

**ClinicalTrials.gov (NCT)**  
Nil known

**Protocol serial number**  
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

## **Study type(s)**

Treatment

## **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(s)**

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

**Key secondary outcome(s)**

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

**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

**Healthy volunteers allowed**

No

**Age group**

Child

**Lower age limit**

8 years

**Upper age limit**

14 years

**Sex**

All

**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

## ROR

<https://ror.org/02x1vjk79>

# Funder(s)

## Funder type

University/education

## Funder Name

Pontifícia 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

Published as a supplement to the results publication

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>			30/05/2023	No	Yes