

# Partial treatment of the root canal of children's teeth with different materials

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<b>Registration date</b> 21/06/2017	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 11/07/2023	<b>Condition category</b> Oral Health	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Milk teeth (also known as primary or baby teeth) are temporary teeth in children which fall out before permanent teeth emerge. They are more fragile than permanent ones because they have a thinner layer of enamel recovering them. When milk teeth get a cavity, this can cause the tooth to decay quickly, which worries the parents because the child fails to exercise normally, reports pain and difficulty feeding, even needing to leave the school to solve this situation. The large, open cavities over a long period have a close proximity to the tissues of the tooth nerve, making the child to feel pain. With this, it is often necessary to treat this nerve of the tooth by a technique called pulpotomy to try to save the tooth, so that the child can chew. In addition, the milk tooth will serve as a guide for the permanent tooth to erupt. Calcium hydroxide can be helpful when placed in the wound as paste to improve healing. The aim of this study is to see if a calcium hydroxide (CH) mixtures placed in the tooth area can improve the healing of the tooth.

### Who can participate?

Children aged five to eight who have their primary molars

### What does the study involve?

Participants are randomly allocated to one of three groups. Those in the first group receive the standard pulpotomy but have their a paste mixed with a gray mineral trioxide aggregate in the wound. Those in the second group receive a paste containing calcium hydroxide mixed with saline (salt water) placed in the wound. Those in the last group receive a paste mixed by calcium hydroxide with polyethylene glycol. Participants are followed up three, six and 12 months after the procedure to see measure the success of the procedures.

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

Participants may benefit from having dental treatment and long term follow up. There are risks with the procedure failing and requiring a pulpectomy (a more invasive technique).

### Where is the study run from?

Federal University of Alfenas School of Dentistry (Brazil)

When is the study starting and how long is it expected to run for?  
January 2013 to July 2015

Who is funding the study?  
Federal University of Alfenas (Brazil)

Who is the main contact?  
Professor Ana Beatriz Silveira Moretti  
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## Contact information

**Type(s)**  
Scientific

**Contact name**  
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## Additional identifiers

## Study information

**Scientific Title**  
Evaluation of pulpotomies in primary teeth with mineral trioxide aggregate and calcium hydroxide associated with different vehicles: Clinical and radiographic outcomes

**Study objectives**  
When calcium hydroxide (CH) is mixed with a viscous vehicle, it dissociates more slowly thus minimizing the dispersion of CH into the tissues and maintaining the paste in the desired area for longer periods. The CH mixed with aqueous promotes high solubility when in direct contact with tissues and fluids being quickly resorption by macrophages revealing an increase in failure rates over the follow-ups.

**Null hypothesis:**  
There will be no difference in between treatment groups (CH mixed with vehicle aqueous X CH mixed with a viscous vehicle) compared to the MTA.

**Ethics approval required**  
Old ethics approval format

**Ethics approval(s)**

## **Study design**

Prospective single-center randomized controlled trial

## **Primary study design**

Interventional

## **Study type(s)**

Treatment

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

Ideal capping agent for pulpotomy in primary teeth

## **Interventions**

Participants are randomly allocated to one of three groups through a computer generated randomization list.

Group 1 (Control): After local anesthesia and rubber dam isolation, carries are removed (dental decay/cavities) with a hand piece with a round bur. The pulp chambers are opened with a round carbide bur. Full coronal pulp tissues are manually removed with an excavator and are irrigated with a saline solution in order to clear the debris. The wound is continuously irrigated with a saline solution until bleeding ceases. In this group, a paste made containing gray mineral trioxide aggregate (MTA) (Ângelus, Londrina, PR, Brazil) powder with a sterile saline at a ratio of 1:1 is placed in the pulp chamber.

Group 2 (Calcium hydroxide and saline): After local anesthesia and rubber dam isolation, carries are removed (dental decay/cavities) with a hand piece with a round bur. The pulp chambers are opened with a round carbide bur. Full coronal pulp tissues are manually removed with an excavator and are irrigated with a saline solution in order to clear the debris. The wound is continuously irrigated with a saline solution until bleeding ceases. In this group, a paste is made containing of calcium hydroxide P.A. calcium hydroxide P.A. (Biodinâmica Química e Farmacêutica Ltda., Ibiporã, PR, Brazil) with sterile saline at 1:1 powder/saline ratio and is placed in the pulp chamber.

Group 3 (Calcium hydroxide and polyethylene glycol (PEG)): After local anesthesia and rubber dam isolation, carries are removed (dental decay/cavities) with a hand piece with a round bur. The pulp chambers are opened with a round carbide bur. Full coronal pulp tissues are manually removed with an excavator and are irrigated with a saline solution in order to clear the debris. The wound is continuously irrigated with a saline solution until bleeding ceases. In this group, the pulp tissue was dressed with a paste obtained by mixing calcium hydroxide P.A. with PEG at 1:1 powder/solution ratio.

In all groups, a layer of cement-cured calcium hydroxide (Biodinâmica Química e Farmacêutica Ltda., Ibiporã, PR, Brazil) was placed prior to restoration with glass-ionomer cement (Vitremex; 3M ESPE, São Paulo, SP, Brazil). This study takes 24 months, with each intervention taking 12 months and the follow-up takes 12 months.

## **Intervention Type**

Other

**Primary outcome(s)**

1. Clinical success and failures are measured using clinical evaluations at three, six and 12 months
2. Radiographic successes are measured using x-rays at three, six and 12 months

**Key secondary outcome(s)**

There are no secondary outcome measures.

**Completion date**

02/07/2015

**Eligibility****Key inclusion criteria**

1. Mandibular primary first or second molar of children between the ages of 5 and 8 years old
2. No more than two mandibular primary molar teeth with vital pulp and no history of pain
3. Clinical macroscopic appearance of the dental pulp (adequate consistency, bright red-colored pulp and cut resistance) thus requiring a pulpotomy therapy
4. No clinical or radiographic evidence of pulp degeneration, such as excessive bleeding, internal root resorption, inter-radicular and/or furcal bone destruction
5. No physiological root resorption of more than one-third, as observed in periapical radiographies
6. The possibility of proper restoration of the teeth

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Child

**Lower age limit**

5 years

**Upper age limit**

8 years

**Sex**

All

**Total final enrolment**

45

**Key exclusion criteria**

1. Excessive pulp bleeding 5 minutes after removal
2. Dark red colored pulp
3. Little cut resistance
4. Presence of systemic pathology
5. Any history of allergic reaction to latex, local anaesthetics or the components of the test pulp

dressing agents

6. Teeth with more than 2/3 of radicular resorption

**Date of first enrolment**

20/07/2013

**Date of final enrolment**

01/09/2013

## **Locations**

**Countries of recruitment**

Brazil

**Study participating centre**

**Federal University of Alfenas School of Dentistry**

Minas Gerais

Rua Gabriel Monteiro da Silva 700

Alfenas - Minas Gerais

Brazil

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## **Sponsor information**

**Organisation**

Federal University of Alfenas

**ROR**

<https://ror.org/034vpja60>

## **Funder(s)**

**Funder type**

University/education

**Funder Name**

Federal University of Alfenas

## **Results and Publications**

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from [ana.moretti@unifal-mg.edu.br](mailto:ana.moretti@unifal-mg.edu.br)

## IPD sharing plan summary

Not provided at time of registration

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		20/05/2019	11/07/2023	Yes	No