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

Submission date
05/02/2017

Recruitment status
No longer recruiting

Registration date
21/06/2017

Overall study status
Completed

Last Edited
11/07/2023

Condition category
Oral Health

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

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)
Ethics Committee of School of Dentistry, Federal University of Alfenas, 03/06/2013. ref: 15304613.1.0000.5142

Study design
Prospective single-center randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet

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 a 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 (Vitremer; 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 measure
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

Secondary outcome measures
There are no secondary outcome measures.

Overall study start date
10/01/2013

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

Age group

Child

Lower age limit
5 Years

Upper age limit
8 Years

Sex
Both

Target number of participants
Forty-five primary molars in children with mean age of 6 years and 5 months were allocated to the three treatment groups (15 teeth per group).

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
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Sponsor information

Organisation
Federal University of Alfenas

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Sponsor type
University/education

Website
www.unifal-mg.edu.br

ROR
https://ror.org/034vpja60

Funder(s)

Funder type
University/education

Funder Name
Federal University of Alfenas

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
10/03/2017

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

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Results article	20/05/2019	11/07/2023	Yes	No