ISRCTN16209990 https://doi.org/10.1186/ISRCTN16209990

Endodontic treatment of anterior primary teeth in different sessions

Submission date
25/07/2017

Recruitment status
No longer recruiting

Registration date
22/09/2017

Overall study status
Completed

Last Edited
01/04/2019

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
A pulpectomy is a procedure that removes infected or diseased pulp (the inside material in a tooth) in order to save the tooth from being pulled. After the pulp is removed, the area inside the tooth is disinfected and then filled with a material. When doing this in young children with their primary (also known as baby) teeth, it is important to do this as quickly as possible in order to not interfere with the child's development. The pulpectomy treatment could be done in one or two sessions. In a two session procedure, the filling amterial is put in the tooth later. The aim of this study is to see is the procedure will have good results when done in one session as it does in two sessions.

Who can participate?
Children aged two to six years old who require dental treatment in the upper front teeth.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive the treatment in only one session. Those in the second group receive the treatment over two sessions, as they return 30 days after the initial treatment for it to be finalised. Participants are followed up one, two, three, six and 12 months after their treatment to measure the success rates of their treatments.

What are the possible benefits and risks of participating?
Participants may benefit from having their primary teeth treated which allows them to stay in the mouth longer until they naturally fall out. In addition, participants may benefit from free assistance at the pediatric dentistry clinic, with periodic oral health guidelines, which will contribute to the quality of life of their entire family. There may be some risks such as some discomforts related to endodontic techniques may occur, such as sensitivity at the time of anesthesia, discomfort due to anesthetic sensation, adverse reaction causing crying according to the patient, not knowing the procedures used, relative fatigue as a result of the procedure being complex and of greater duration.

Where is the study run from?
Federal University of Santa Maria (Brazil)

When is the study starting and how long is it expected to run for?
August 2016 to May 2017

Who is funding the study?
Brazilian Federal Agency for the Support and Evaluation of Graduate Education, Coordination for the Improvement of Higher Education Personnel, CAPES (Brazil)

Who is the main contact?
Mrs Lisara Tosatto Pinto
lisaratp@smail.ufsm.br

Contact information

Type(s)
Public

Contact name
Mrs Lisara Tosatto Pinto

ORCID ID
https://orcid.org/0000-0003-0234-5734

Contact details
Federal University of Santa Maria
Floriano Peixoto
1184
Departament of Stomatology
Santa Maria
Brazil
97500-124

Additional identifiers

Protocol serial number
U1111-1194-1105

Study information

Scientific Title
Single-visit versus multiple-visit endodontic treatment of anterior upper primary teeth with calcium hydroxide as intracanal dressing: Randomized clinical trial

Study objectives
Null hypothesis:
There is no difference between the two groups.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of Federal University of Santa Maria, 03/08/2016, ref: CAAE: 57327516.7.000.5346

Study design
Double blind two armed randomised parallel controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Endodontic treatment of anterior primary teeth.

Interventions
Participants are allocated to one of two groups after opening of brown envelopes, previously organized within a randomised sequence.

The intervention group receive local anesthesia (Lidocaine 2%), absolute isolation, chemical-mechanical preparation of the root canals with Milton's solution, second-series endodontic files, final irrigation with saline solution 0.9%, paste filling (Calcium Hydroxide PA + zinc oxide powder and propylene glycol), gutta percha blade and final restoration with composite resin.

The control group also receive local anesthesia (Lidocaine 2%), absolute isolation, chemical-mechanical preparation of the root canals with Milton's solution, second-series endodontic files, final irrigation with saline solution 0.9% and paste filling (Calcium Hydroxide PA + zinc oxide powder and propylene glycol), but the restoration is temporary with glass ionomer cement. After 30 days, there is a reintervention in the control group with the exchange of the obturator material, and then the final restoration is done with composite resin.

The operator performs blindly during the procedure, since only the group becomes aware of the final moment of use of the sealing paste. The cases have their performances evaluated at 30, 60, 90 days, six months and one year through clinical and radiographic exams.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Radiographic lesions are measured using the periapical radiography at the beginning and the end of the study.

Key secondary outcome(s)
Fistula is measured using visual scale at the beginning and the end of the study.

Completion date
29/05/2017

Eligibility

Key inclusion criteria
1. Upper anterior primary teeth
2. Radiographic alteration suggestive of periapical lesion
3. Cavity that allows restorative recovery
4. Without any previous pulp treatment
5. Good systemic health
6. Between 2 and 6 years of age

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
2 years

Upper age limit
6 years

Sex
All

Key exclusion criteria
1. Root resorption with more than 2/3
2. Radiographic rupture of the pericoronary sac of the permanent successor
3. Syndromes
4. Systemic changes

Date of first enrolment
07/03/2016

Date of final enrolment
06/03/2017

Locations

Countries of recruitment
Brazil

Study participating centre
Federal University of Santa Maria
Floriano Peixoto
1184 Departament of Stomatology
Santa Maria

Brazil
97500-124

Sponsor information

Organisation
CAPES

ROR
https://ror.org/00x0ma614

Funder(s)

Funder type
Government

Funder Name
Coordenação de Aperfeiçoamento de Pessoal de Nível Superior

Alternative Name(s)
Brazilian Federal Agency for the Support and Evaluation of Graduate Education, Coordination for the Improvement of Higher Education Personnel, CAPES Foundation, Capes - Ministério da Educação, Coordinación de la formación del personal de nivel superior (Brasil), CAPES

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Brazil

Results and Publications

Individual participant data (IPD) sharing plan
The type of data and participant level are stored. Among them, there are the clinical sheet, the free and informed consent term, the confidentiality term and the institutional authorization term.

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			01/04/2019	No	Yes