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Direct pulp capping in primary molars: a feasibility study

Submission date
11/10/2018

Recruitment status
No longer recruiting

Registration date
25/10/2018

Overall study status
Completed

Last Edited
17/11/2023

Condition category
Oral Health

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Exposures of the dental pulp (the centre of the tooth) are common in dental practice and can be challenging especially in primary (baby) teeth. Direct pulp capping (DPC) is a technique used to cover the exposed pulp. It is still controversial as a treatment. However, calcium hydroxide (CH) is considered the gold standard in dental pulp treatments. The introduction of a combination of antibiotics could be promising in pulp treatments. However, improving DPC outcomes would provide an easier and less invasive treatment option for pulp exposures in these teeth. The aim of this study is to assess the feasibility of conducting a future trial on DPC using 3Mix-MP (triple antibiotic paste) compared with calcium hydroxide, and to estimate the number of participants needed for the main trial on the basis of the success rate.

Who can participate?
Children who have primary molars (back teeth) with large carious lesions (cavities) that could be restored with composite

What does the study involve?
The participants' teeth are randomly allocated into two groups to be treated with DPC with either 3Mix-MP or calcium hydroxide (CH). All teeth are restored with composite resin and assessed at 3 and 6 months after treatment.

What are the possible benefits and risks of participating?
Treating these teeth could prevent inflammation/abscesses and the associated signs like pain and swelling. No harms are encountered since all failed cases are treated with another method (non-instrumental endodontic treatment or traditional pulpectomy).

Where is the study run from?
Tishreen University (Syria)

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

Who is funding the study?
Tishreen University (Syria)

Who is the main contact?
1. Dr Nabih Raslan
2. Dr Hasan Ali

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

U1111-1222-2654

Study information

Scientific Title
Direct pulp capping (DPC) in primary molars using three antibiotics combination 3mix-mp: a randomized controlled pilot trial

Study objectives
Is conducting a large randomized clinical trial feasible and what is the proper sample size?

Ethics approval required
Old ethics approval format

Ethics approval(s)
The institutional review board of Tishreen University, 02/08/2016, Approval No. 3179

Study design
Pilot randomized double-blind parallel two-arm control trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Management of large carious lesions in primary teeth

Interventions
Twenty molars in eight cooperative healthy children were randomly allocated into two groups using a simple randomization process. In both groups, teeth were anesthetized and isolated with a rubber dam. All carious tissues were removed using a small round bur mounted on a high-speed handpiece and copious water supply.

After observing an exposure site, a cotton pellet soaked with sodium hypochlorite was applied for five minutes.The dressing agent was chosen randomly and the teeth were divided into two groups: 3Mix-MP (Group A) and calcium hydroxide powder mixed with saline CH (Group B). The dressing agent was prepared in creamy form and was applied to the exposure site before it was gently pressed into a thin layer on the cavity floor using a cotton pellet. The agent was covered

with a thin layer of light cured calcium hydroxide. Composite resin restorations were placed, and then were finished after removing the rubber dam with diamond finishing burs; consequently, polishing was performed using silicone polishers.

The participants were asked to attend follow-up examination, and were clinically evaluated at 3 and 6 months post-treatment and were evaluated radiographically at 6 months.

Intervention Type
Procedure/Surgery

Primary outcome measure
Feasibility, estimated using the following measurements:
1. Proportion of eligible children among those examined, calculated after completion of the assigned number of participants
2. Proportion of children who completed the 6-month follow-up among those randomized, calculated after completion of the assigned period

Secondary outcome measures
Success rates of the materials, which will be used to calculate the sample size for the definitive randomized controlled trial. Criteria used: absence/presence of clinical and radiographic signs, proportions calculated using simple formulas. Measured at the end of the treatment session as a baseline; the participants were clinically evaluated at 3 and 6 months post-treatment and evaluated radiographically after 6 months

Overall study start date
17/08/2016

Completion date
23/06/2017

Eligibility

Key inclusion criteria
1. Cooperative healthy children
2. Vital primary molars with large carious lesions that could be restored with composite
3. No history of spontaneous pain, pathologic mobility, redness or swelling of the vestibule, draining sinus tracts, or sensitivity to vestibular palpation
4. Absence of internal or external root resorption or inter-radicular/apical radiolucency
5. Both children and their parents had to be able to attend a 6-month follow-up procedure

Participant type(s)
Patient

Age group
Child

Sex
Both

Target number of participants

20

Total final enrolment
17

Key exclusion criteria
Any clinical or radiographic signs indicating non-vital teeth

Date of first enrolment
20/08/2016

Date of final enrolment
16/12/2016

Locations

Countries of recruitment
Syria

Study participating centre
Tishreen University
Department of Pediatric Dentistry
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Sponsor information

Organisation
Tishreen University

Sponsor details
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Sponsor type
University/education

Website
http://www.tishreen.edu.sy/

ROR

https://ror.org/04nqts970

Funder(s)

Funder type
University/education

Funder Name
Tishreen University

Results and Publications

Publication and dissemination plan
Planned submission to Pilot and Feasibility Studies journal as soon as trial is registered.

Intention to publish date
31/12/2018

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during this study will be included in the subsequent results publication. Individual participant data that underlie the results, after deidentification (text, tables, figures, and appendices), would be available immediately after publication from raslan.nabih@tishreen.edu.sy.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		04/02/2021	27/09/2021	Yes	No
Abstract results	P026	01/09/2019	17/11/2023	No	No