Direct pulp capping in primary molars

Submission date 29/10/2018	Recruitment status No longer recruiting	<pre>[] Prospect [] Protocol</pre>
Registration date 31/10/2018	Overall study status Completed	[_] Statistica[X] Results
Last Edited 05/02/2021	Condition category Oral Health	[_] Individua

tively registered

- al analysis plan
- al participant data

Plain English summary of protocol

Background and study aims

Vital baby teeth with deep caries (decay and crumbling) can be treated in a variety of ways. When exposure of the pulp (the centre of the tooth) occurs in these teeth, a method called direct pulp capping (DPC) may be an excellent treatment of choice, as it might prevent unnecessary loss of the tooth structure. DPC builds a barrier over the site of exposure to protect the pulp. Calcium hydroxide is commonly used for DPC. However, using a combination of three antibiotics, caled 3Mix-MP, could reduce the inflammation and infection, and enhance the healing of the pulp. This study aims to compare the effectiveness of using 3Mix-MP and calcium hydroxide for DPC.

Who can participate? Children who have primary molars with large caries

What does the study involve?

Chosen teeth are randomly allocated into two groups for DPC treatment with either 3Mix-MP or calcium hydroxide (CH). All teeth are assessed at 3, 6, 9 and 12 months after treatment and will be assessed radiographically after 6 and 12 months.

What are the possible benefits and risks of participating?

The treatment may prevent inflammation and abscesses, along with symptoms such as pain and swelling.

There are no known risks to participants, as any failed treatments will be re-done using another method.

Where I the study run from? Department of Pediatric Dentistry, Tishreen University Latakia (Syria)

When is the study starting and how long is it expected to run for? July 2016 to February 2019

Who is funding the study? Tishreen University (Syria) Who is the main contact? 1. Dr. Nabih Raslan (rasln.nabih@tishreen.edu.sy) 2. Dr. Hasan Ali (hasan.h.ali@outlook.com)

Contact information

Type(s) Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

REF: 179/20

Study information

Scientific Title

Direct pulp capping (DPC) in primary molars using a combination of three antibiotics (3Mix-MP): a randomized parallel controlled trial

Acronym Direct pulp capping (DPC)

Study objectives

Is using 3mix-mp in direct pulp capping in primary molars more effective than using calcium hydroxide?

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

Interventional double-blind two-arm randomised parallel controlled trial

Primary study design Interventional

Secondary study design Randomised controlled trial

Study setting(s) Hospital

Study type(s) Treatment

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Management of large carious lesions in primary teeth

Interventions

Participants are randomly allocated to either group A or group B using a simple randomisation technique.

Group A receive direct pulp capping using 3Mix-MP, whereas group B receive direct pulp capping using calcium hydroxide.

Participants are asked to attend follow-up examinations, with clinical evaluations at 3, 6, 9 and 12 months post-treatment and radiographic evaluations at 6 and 12 months.

Intervention Type

Procedure/Surgery

Primary outcome measure

Clinical success rate of the materials, with treatment considered to be a success if the following clinical signs are absent:

- 1. Spontaneous pain
- 2. Redness or soft tissue swelling
- 3. Mobility
- 4. Draining sinus tracts

5. Sensitivity to vestibular palpation

Teeth will be assessed clinically at the baseline and 3, 6, 9 and 12 months post-treatment.

Secondary outcome measures

Radiographic success rate of the materials, with the treatment considered to be a success if the following radiographic signs are absent:

1. Internal or external pathological root resorption

2. Inter-radicular/periapical radiolucency

Teeth will be assessed radiographically at the baseline and at 6 and 12 months post-treatment.

Overall study start date

17/07/2016

Completion date

15/02/2019

Eligibility

Key inclusion criteria

1. Cooperative healthy children

2. Aged 5-11 years

3. Vital primary molars with large carious lesions that could be restored with composite

4. No history of spontaneous pain, pathological mobility, redness or swelling of the vestibule, draining sinus tracts, or sensitivity to vestibular palpation

5. Absence of internal or external root resorption or inter-radicular/apical radiolucency

6. Both children and their parents are able to attend a 12-month follow-up procedure

Participant type(s)

Healthy volunteer

Age group Child

Lower age limit 5 Years

Upper age limit

11 Years

Both

Target number of participants 36

Total final enrolment 17

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

Date of first enrolment 15/08/2017

Date of final enrolment 25/03/2018

Locations

Countries of recruitment Syria

Study participating centre Tishreen University Department of Pediatric Dentistry Lattakia Syria 00963

Sponsor information

Organisation Tishreen University

Sponsor details Department of Paediatric Dentistry Faculty of Medical Dentistry Lattakia Syria 00963

Sponsor type University/education

Website

http://www.tishreen.edu.sy

ROR https://ror.org/04nqts970

Funder(s)

Funder type Not defined

Funder Name

Tishreen University, Latakia. Syria (ref: 4075/20).

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer reviewed journal

Intention to publish date

15/04/2019

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Dr. Nabih Raslan (raslan.nabih@tishreen.edu.sy), from 3 months after publication up to 3 years. Data will be available for researchers who provide a methodological sound proposal.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<u>Poster results</u>	conference abstract	01/09/2019	22/10/2019	No	Νο
<u>Basic results</u>		14/02/2020	14/02/2020	No	Νο
<u>Results article</u>	results	04/02/2021	05/02/2021	Yes	No