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# Direct pulp capping in primary molars

**Submission date**
29/10/2018

**Recruitment status**
No longer recruiting

**Registration date**
31/10/2018

**Overall study status**
Completed

**Last Edited**
05/02/2021

**Condition category**
Oral Health

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


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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

### Sex

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
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# Sponsor information

**Organisation**
Tishreen University

**Sponsor details**
Department of Paediatric Dentistry
Faculty of Medical Dentistry
Lattakia
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**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? |
|---|---|---|---|---|---|
| Poster results | conference abstract | 01/09/2019 | 22/10/2019 | No | No |
| Basic results | results | 14/02/2020 | 14/02/2020 | No | No |
| Results article | | 04/02/2021 | 05/02/2021 | Yes | No |