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The use of a premixed bioceramic material in the pulp cavity of decayed primary teeth in children

Submission date
07/09/2022

Recruitment status
No longer recruiting

Registration date
14/09/2022

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
Deep tooth decay (dental caries) is very common among children. The most common treatment for deep caries in primary molars is pulpotomy, where the uppermost infected pulp inside the tooth is removed and replaced with a medicated filling. A variety of materials are used for pulpotomy including mineral trioxide aggregate (MTA). Newer materials are available in the dental market with better handling and easier application than MTA. NeoPUTTY is a premixed MTA that is being newly introduced for use in primary teeth pulpotomies. This study aims to compare the clinical and radiographic success rate of NeoPUTTy as a pulpotomy material in comparison to a conventional MTA.

Who can participate?
Healthy, cooperative children aged between 4 and 10 years old with one or more primary molars that have deep caries approaching the pulp

What does the study involve?
If the patient has one or more carious primary molars satisfying the inclusion criteria, after obtaining consent they will be enrolled in the study. Teeth will be randomly treated using one of the materials according to the randomization table. All teeth will receive a standardized pulpotomy treatment, then the tooth will be restored with a stainless steel crown. The included teeth will be evaluated clinically and radiographically after 6 and 12 months.

What are the possible benefits and risks of participating?
It is expected that participation in this study will help in enhancing the knowledge of pulp treatment in primary teeth. There are no known risks for the treatment provided. However, we cannot guarantee any unforeseeable risks. Immediate failed pulp therapy is rare but is associated with pain, swelling and/or tenderness when biting on the treated tooth. Long-term failure is mostly associated with a chronic abscess which according to the available data occurs in 5-10% of cases. Any side effect will receive immediate attention and proper treatment according to the standard of care for the condition will be provided.

Where is the study run from?
Dental University Hospital, King Saud University Medical City (Saudi Arabia)

When is the study starting and how long is it expected to run for?
January 2021 to September 2022

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Abeer Alqahtani
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Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CDRC FR0591

Study information

Scientific Title
Evaluation of premixed bioceramic material (NeoPUTTY®) as a pulpotomy material for primary molars: A randomized clinical trial

Study objectives
The null hypothesis is there is no significant difference in the clinical and radiographic success rates between NeoPUTTY® and NeoMTA2® as pulpotomy materials in primary molars

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 25/02/2021, The Institutional Review Board and Ethics Committee of the College of Dentistry Research Center (King Khalid Medical City, King Saud University, Riyadh, Saudi Arabia; +966 11 469 1532; rdeocampo@ksu.edu.sa), ref: E-21-5747

Study design
Interventional randomized double-blind (participants and evaluators) single-center study

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 the contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Dental caries requiring pulpotomy treatment

Interventions
Children aged between 4 and 10 years old attending the pediatric dental clinics at Dental University Hospital, King Khaled Medical City, King Saud University will be screened for teeth with deep caries indicating pulpotomy treatment according to the study inclusion criteria. Consent was obtained parents/legal guardians. Included teeth were randomly divided into two groups (allocation ratio of 1:1): the control group (pulpotomy was performed with NeOMTA2) and the experimental group (pulpotomy performed using NeoPUTTY). Clinical and radiographic evaluations were conducted after 6 and 12 months by two blinded calibrated examiners.

At each follow-up, the treatment was considered a clinical failure if one or more of the following signs and symptoms were present: pain, swelling, pathological mobility, sinus tract, and tenderness to percussion. Also, the treatment was considered a radiographic failure if one of the following signs were present: widening of the periodontal ligaments, internal or external root resorption, furcal and/or periapical radiolucency

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
NeoPUTTY®, NeoMTA2®

Primary outcome measure
Clinical and radiographic success rates of both pulpotomy materials measured using an assessment of signs and symptoms by the examiners at 6 and 12 months follow-up

Secondary outcome measures
Failure type of each group measured by the examiners at 6 and 12 months follow-up

Overall study start date
07/01/2021

Completion date
20/09/2022

Eligibility

Key inclusion criteria
1. Children aged between 4 and 10 years old
2. Healthy (ASA Physical Status Classification System I and II)
3. Cooperative (positive or definitely positive behavior according to Frankl behavior scale)
4. Deep dentin caries approximating or reaching the pulp without any signs or symptoms of pulpal degeneration in one or more primary molar
5. Primary molars clinical inclusion criteria: no history of spontaneous or persistent pain; restorable primary molars with deep carious lesions approximating or reaching the pulp; no

pathological mobility, no tenderness to percussion, no swelling or sinus tract; hemostasis achieved after coronal pulp amputation within 5 minutes
6. Primary molars radiographic inclusion criteria: deep dentin caries approximating or reaching the pulp; no more than two-thirds of physiologic root resorption; no widening of the periodontal ligament space; no pathologic internal or external root resorption; no apical or furcal radiolucency

Participant type(s)
Patient

Age group
Child

Lower age limit
4 Years

Upper age limit
10 Years

Sex
Both

Target number of participants
70 primary molars

Total final enrolment
70

Key exclusion criteria
1. Children with special needs
2. Primary molars with uncontrolled bleeding after coronal pulp amputation

Date of first enrolment
01/05/2021

Date of final enrolment
01/07/2021

Locations

Countries of recruitment
Saudi Arabia

Study participating centre
Dental University Hospital, King Saud University Medical City
P.O BOX 60169
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Sponsor information

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Sponsor type
University/education

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Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

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

Intention to publish date
20/12/2022

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Abeer Alqahtani, abeer.sq@hotmail.com. SPSS data will be available, these data will become available upon request, written consent from participants was obtained, no ethical or legal restrictions.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		15/05/2023	11/07/2023	Yes	No