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

Submission date	Recruitment status No longer recruiting	<ul><li>Prospectively registered</li></ul>		
07/09/2022		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
14/09/2022	Completed	[X] Results		
<b>Last Edited</b> 11/07/2023	<b>Condition category</b> Oral Health	[] 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 abeer.sq@hotmail.com

# Contact information

## Type(s)

Principal investigator

#### Contact name

Dr Abeer Alqahtani

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Principal investigator

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# Additional identifiers

## Clinical Trials Information System (CTIS)

Nil known

## ClinicalTrials.gov (NCT)

Nil known

#### Protocol serial number

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

# Study type(s)

Treatment

# 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(s)

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

# Key secondary outcome(s))

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

#### 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

## Healthy volunteers allowed

No

# Age group

Child

#### Lower age limit

4 years

# Upper age limit

10 years

#### Sex

All

#### 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 Riyadh Saudi Arabia 12372

# Sponsor information

# Organisation

King Saud University

#### **ROR**

https://ror.org/02f81g417

# Funder(s)

# Funder type

Other

#### Funder Name

Investigator initiated and funded

# **Results and Publications**

# 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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes