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Biological properties of white mineral trioxide aggregate mixed with sodium hypochlorite gel

Submission date	**Recruitment status**	[_] Prospectively registered
02/07/2024	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
03/07/2024	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
03/07/2024	Oral Health	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
MTA (mineral trioxide aggregate) is considered the gold standard dressing material for pulpotomy in primary molars However, it has several disadvantages, including difficulty handling the material due to its poor consistency, limited antibacterial activity, short working time, and long setting time when mixed with distilled water. Several in vitro studies suggested mixing the white MTA (WMTA) compound with various additives to improve its properties and reduce the setting time. Among them is sodium hypochlorite (NaOCl) gel, which has good biocompatibility, reduced setting time and improved physical, chemical, and antimicrobial properties. Various studies prove the safety and biocompatibility of the mixture. This study aims to perform a histological evaluation of primary teeth pulpotomy using WMTA mixed with 2.25% NaOCl gel.

Who can participate?
Children aged 8-10 years old with at least 2 bilateral carious first primary molars indicated for pulpotomy and children requiring serial extraction of first primary molars for orthodontic reasons.

What does the study involve?
A total of 24 patients with 48 first primary molars indicated for pulpotomy will be randomly assigned into two groups (n=24) according to the pulp dressing material used:
Group 1 (WMTA + DW): WMTA mixed with distilled water (Rootdent, TehnoDent Co., Belgorod, Russia), will be considered the control group.
Group 2 (WMTA + NaOCl gel): WMTA mixed with 2.25% NaOCl gel (LET'S CLEAN Concentrated Chlorine, DTIC®, Damascus, Syria), will be considered the interventional group.

Each group will be sub-divided into three sub-groups (n=8) according to the follow-up period:
Sub-group I: The serial extraction will be scheduled after 7 days.
Sub-group II: The serial extraction will be scheduled after 30 days.
Sub-group III: The serial extraction will be scheduled after 90 days.

What are the possible benefits and risks of participating?
Participants will benefit from being provided with serial extraction. However, the risks include receiving painful therapy twice.

Where is the study run from?
Damascus University

When is the study starting and how long is it expected to run for?
December 2023 to June 2024

Who is funding the study?
Damascus University

Who is the main contact?
Dr. Mawia Karkoutly, Mawiamaherkarkoutly@hotmail.com

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Biological properties of white mineral trioxide aggregate mixed with 2.25% sodium hypochlorite gel: A randomized controlled trial

Study objectives
The null hypothesis is that the mixture with 2.5% NaOCl gel will not improve the biological properties of the white mineral trioxide aggregate compared with distilled water.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 05/01/2024, Faculty of Dental Medicine Biomedical Research Ethics Committee (Damascus University, Mezzeh highway, Damascus, -, Syria; +963 113 392 6091; dean.dent@damascusuniversity.edu.sy), ref: 1297/2024

Study design
Randomized triple-blinded split-mouth active-controlled clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Dental clinic, Laboratory, University/medical school/dental school

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Dental caries

Interventions
This study will be a randomized, triple-blinded, split-mouth, active-controlled clinical trial. Periapical radiographic imaging will be performed using an intraoral periapical sensor (i-sensor, Guilin Woodpecker Medical Instrument Co., LTD., Guilin, China). A simple randomization method will be used by flipping a coin for each patient. According to the inclusion criteria, a total of 24 patients with 48 first primary molars indicated for pulpotomy will be randomly assigned into two groups (n=24) according to the pulp dressing material used:
• Group 1 (white mineral trioxide aggregate [WMTA] + DW): WMTA mixed with distilled water (Rootdent, TehnoDent Co., Belgorod, Russia), will be considered the control group.
• Group 2 (WMTA + NaOCl gel): WMTA mixed with 2.25% NaOCl gel (LET'S CLEAN Concentrated Chlorine, DTIC®, Damascus, Syria), will be considered the interventional group.

Each group will be sub-divided into three sub-groups (n=8) according to the follow-up period:
• Sub-group I: The serial extraction will be scheduled after 7 days.
• Sub-group II: The serial extraction will be scheduled after 30 days.
• Sub-group III: The serial extraction will be scheduled after 90 days.

Topical anesthetic (Iolite, Dharma Research Inc., Florida, United States) will be applied at the site of needle insertion then local anesthetic solution (2% Lidocaine HCL Injection, Huons Co., Ltd, Seongnam, Korea) will be deposited using a dental carpule syringe (Dental carpule syringe, Dental Laboratorio, China) and a 27-gauge x 21 mm needle (Disposable Dental Needle, Shanghai Dochem Industries Co., Ltd., Shanghai, China). A rubber dam (Sanctuary®, Perak, Malaysia) and a saliva ejector (Disposable Transparent Surgical Dental Saliva Ejectors China, Andent Dental Co., Ltd., Hebei) will be used for isolation. Caries lesions will be removed, and the pulp chamber will be deroofed using a round tungsten carbide cavity bur (Round E 0123, Dentsply Maillefer, Ballaigues, Switzerland) in an air turbine handpiece (NSK PANA-AIR, NSK Nakanishi Inc., Tochigi-ken, Japan) with copious irrigation. Coronal pulpotomy will be performed using a slow-speed endodontic opening cutter carbide bur (Excavabur E123A, Dentsply Maillefer, Ballaigues, Switzerland) in a contra-angle handpiece (NAC-EC, NSK Nakanishi Inc., Tochigi-ken, Japan). The pulp chamber will be thoroughly irrigated, and hemostasis will be achieved using a moist cotton pellet with normal saline (SODIUM CHLORIDE 0.9% MIAMED, Miamed Pharmaceutical Industry, Damascus, Syria) for 5 minutes. In the control group, WMTA powder will be mixed with distilled water in a 3:1 powder-to-liquid ratio, and then the pulp will be stamped with a 3 mm thick layer of MTA. In the interventional group, WMTA will be mixed with 2.25% NaOCl gel in a 3:1 powder-to-gel ratio. In both study groups, the cavity will be sealed with glass ionomer cement (RX Glass Ionomer Cement, Stardent Equipment Co., Ltd., Guangdong, China), and then the tooth will be restored with a stainless-steel crown (Kids Crown, Shinhung, Seoul, Korea) at the same appointment. Extraction will be scheduled after 7, 30, and 90 days for histological evaluation.

Each sample will be stored in 10% buffered formalin solution (10% Neutral Buffered Formalin, Thomas Scientific LLC, New Jersey, United States) for 48 hours at room temperature for fixation, and then it will be demineralized in Morse's solution (Morse Solution, FUJIFILM Wako Pure Chemical Co., Hong Kong, China), which is an aqueous solution of 22.5% formic acid and 10% sodium citrate. Each specimen will be embedded in a paraffin wax block (Clear Paraffin Block, EverBio Technology INC., New Taipei City, Taiwan), and then the paraffin-embedded wax blocks will be sectioned at 5 μm using a semi-motorized rotary microtome (Leica RM2145 Microtome, GMI, New Jersey, United States). The sectioned samples will be stained with hematoxylin and eosin (H&E Staining Kit, Abcam, England, United Kingdom), and the histological samples will be evaluated using a light microscope (Leica Microscope DM2500, Leica, Hesse, Germany) at 400× magnification by two blinded operators. Cohen's Kappa coefficient values of intra-examiner and inter-examiner reliability will be > 0.8.

The following primary outcome measures will be assessed:
Odontoblastic integrity
• Grade 0 = Normal tissue morphology.
• Grade 1 = Mild odontoblastic disorganization. Normal morphology of central pulp tissue.
• Grade 2 = Moderate odontoblastic disorganization.
• Grade 3 = Severe odontoblastic disorganization. Complete morphological disorganization of pulp tissue.
• Grade 4 = Pulp necrosis.
Pulp tissue hemorrhage
• Grade 0 = No hemorrhage.
• Grade 1 = Mild hemorrhage. A few scattered red blood cells.
• Grade 2 = Moderate hemorrhage. Some clusters or red blood cells.
• Grade 3 = Severe hemorrhage. Extensive infiltration of red blood cells.
Pulp fibrosis
• Grade 0 = No pulp fibrosis.
• Grade 1 = Mild pulp fibrosis. Thin collagen fibers.
• Grade 2 = Moderate pulp fibrosis.

• Grade 3 = Severe pulp fibrosis. Thick collagen fibers.
Dentin bridge formation
• Grade 0 = No dentin bridge formation.
• Grade 1 = Initial dentin bridge formation. Dentin bridge extended to < ½ of the exposure site
• Grade 2 = Partial dentin bridge formation. Dentin bridge extended to > ½ of the exposure site.
• Grade 3 = Complete dentin bridge formation. Continuity of dentin bridge.
Pulp calcification
• Grade 0 = No pulp calcification.
• Grade 1 = Single small calcification.
• Grade 2 = Multiple small calcifications.
• Grade 3 = Single large calcification.
• Grade 4 = Multiple large calcifications.

Intervention Type
Procedure/Surgery

Primary outcome measure
The following primary outcomes will be measured using histology after 7, 30, and 90 days:
1. Odontoblastic integrity
2. Pulp tissue hemorrhage
3. Pulp fibrosis
4. Dentin bridge formation
5. Pulp calcification

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
05/12/2023

Completion date
02/06/2024

Eligibility

Key inclusion criteria
1. Children aged 8-10 years
2. Children with at least 2 bilateral carious first primary molars indicated for pulpotomy
3. Children require serial extraction of first primary molars for orthodontic reasons

Participant type(s)
Patient

Age group
Child

Lower age limit
8 Years

Upper age limit

10 Years

Sex
Both

Target number of participants
24

Total final enrolment
24

Key exclusion criteria
1. Children with systematic diseases and/or allergies to the anesthetic agents
2. Children with clinical and radiographical signs of pulp necrosis in the targeted teeth and/or unrestorable teeth
3. Children with nocturnal and/or spontaneous pain

Date of first enrolment
10/01/2024

Date of final enrolment
12/02/2024

Locations

Countries of recruitment
Syria

Study participating centre
Department of Pediatric Dentistry and the Department of Oral and Maxillofacial Pathology
Faculty of Dentistry, Damascus University, Al Mazzeh Street
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Sponsor information

Organisation
Damascus University

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Sponsor type
University/education

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ROR
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Funder(s)

Funder type
University/education

Funder Name
Damascus University

Alternative Name(s)
University of Damascus, , DU

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Syria

Results and Publications

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

Intention to publish date
01/09/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Mawiamaherkarkoutly@hotmail.com. The type of data that will be shared includes anonymised demographic information that will be available after publication. Consent from participants was required and obtained.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file			03/07/2024	No	No