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Clinical and radiographical outcomes after pulpotomies using mineral trioxide aggregate mixed with distilled water or 2.25% sodium hypochlorite gel

Submission date 23/01/2025	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 23/01/2025	**Overall study status** Completed	
Last Edited 23/01/2025	**Condition category** Oral Health	

Plain English summary of protocol

Background and study aims
The reduced working time of MTA might be improved by using different vehicles or additives. NaOCl gel is an additive for MTA that improves its chemical and physical characteristics, enhances its handling and antibacterial properties, and significantly decreases the setting time while maintaining biocompatibility. Thus, this study sought to compare the outcomes of pulpotomies performed in primary teeth using WMTA mixed with 2.25% NaOCl gel or WMTA mixed with DW. The null hypothesis was that the WMTA mixed with 2.25% NaOCl gel did not enhance the clinical and radiographic outcomes compared to WMTA mixed with DW.

Who can participate?
Participants aged between 5 and 10 years who were cooperative and indicated for a pulpotomy treatment on their second primary molars were included in the study.

What does the study involve?
The selected participants, who had 40 second primary molars that required pulpotomy, were randomly assigned to one of two groups (n = 20) according to the pulp dressing material used:
Group 1 (WMTA + NaOCl gel): WMTA (Rootdent, TehnoDent Co., Belgorod, Russia) mixed with 2.25% NaOCl gel (LET'S CLEAN Concentrated Chlorine, DTIC®, Damascus, Syria) was categorized as the interventional group.
Group 2 (WMTA + DW): WMTA combined with DW was designated the control group.

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

Where is the study run from?
Damascus University (Syria)

When is the study starting and how long is it expected to run for?
January 2024 to January 2025

Who is funding the study?
Damascus University (Syria)

Who is the main contact?
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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
Clinical and radiographical outcomes after pulpotomies using mineral trioxide aggregate mixed with distilled water or 2.25% sodium hypochlorite gel: a randomized controlled clinical trial

Study objectives

White mineral trioxide aggregate (WMTA) mixed with 2.25% sodium hypochlorite (NaOCl) gel will enhance the clinical and radiographic outcomes compared to WMTA mixed with distilled water (DW).

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 12/01/2024, The Biomedical Research Ethics Committee (Mazzeh, Damascus, -, Syria; +963 (11) 33923223; dean.dent@damascusuniversity.edu.sy), ref: 1254/2024

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

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
University/medical school/dental school

Study type(s)
Treatment

Participant information sheet

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

Interventions
Two experienced pediatric dentists (ICC > 0.8) selected 20 participants from 31 who were referred to the Department of Pediatric Dentistry. The selected participants, who had 40 second primary molars that required pulpotomy, were randomly assigned to one of two groups (n = 20) according to the pulp dressing material used:
• Group 1 (WMTA + NaOCl gel): WMTA (Rootdent, TehnoDent Co., Belgorod, Russia) mixed with 2.25% NaOCl gel (LET'S CLEAN Concentrated Chlorine, DTIC®, Damascus, Syria) was categorized as the interventional group.
• Group 2 (WMTA + DW): WMTA combined with DW was designated the control group.
Randomization and blinding
The study was a triple-blinded trial, ensuring that the dentist, participants, and outcome assessors were unaware of the group assignments. A blinded investigator implemented a simple randomization method, using a coin toss for each participant. Subsequently, the second primary molars were allocated at random to either the control group or the intervention group for each participant, using a split-mouth design.

Treatment procedure
A diagnostic periapical radiograph was obtained using an intraoral periapical sensor (i-sensor, Guilin Woodpecker Medical Instrument Co., LTD., Guilin, China). Following the administration of sufficient anesthesia and achieving proper isolation, the decay was excavated, and a coronal

pulpotomy was carried out. Hemorrhage was managed by applying a sterile cotton pellet soaked in normal saline and exerting pressure on the pulp stump for 5 minutes. In the control group, WMTA powder was combined with distilled water at a ratio of 3:1, powder-to-liquid, and subsequently, a 3mm thick layer of MTA was applied to the pulp. In the interventional group, WMTA was mixed with a 2.25% NaOCl gel at a 3:1 ratio of powder to gel. A stainless steel crown (SSC) (Kids Crown, Shinhung, Seoul, Korea) was the final restoration and immediately delivered after the treatment. Follow-up Intervals were planned at 3, 6, and 12 months.

Intervention Type
Procedure/Surgery

Primary outcome measure
1. Spontaneous pain is measured using a visual analog scale (VAS) at baseline, 3 months, 6 months, and 12 months
2. Pain on percussion is measured using a percussion test at baseline, 3 months, 6 months, and 12 months
3. Tooth mobility is measured using the Miller Mobility Index at baseline, 3 months, 6 months, and 12 months
4. Abscesses are measured using clinical examination at baseline, 3 months, 6 months, and 12 months
5. Fistulas are measured using clinical examination at baseline, 3 months, 6 months, and 12 months
6. Exfoliation of the treated tooth is measured using clinical examination at baseline, 3 months, 6 months, and 12 months
7. Furcal radiolucency is measured using periapical radiographic evaluation at baseline, 3 months, 6 months, and 12 months
8. Internal root resorption is measured using periapical radiographic evaluation at baseline, 3 months, 6 months, and 12 months
9. External root resorption is measured using periapical radiographic evaluation at baseline, 3 months, 6 months, and 12 months
10. Widening of the periodontal ligament is measured using periapical radiographic evaluation at baseline, 3 months, 6 months, and 12 months
11. Canal obliteration is measured using periapical radiographic evaluation at baseline, 3 months, 6 months, and 12 months

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
12/01/2024

Completion date
22/01/2025

Eligibility

Key inclusion criteria
1. Participants aged between 5 and 10 years
2. Participants who were cooperative
3. Participants indicated for a pulpotomy treatment on their second primary molars

Participant type(s)
Healthy volunteer

Age group
Child

Lower age limit
5 Years

Upper age limit
10 Years

Sex
Both

Target number of participants
20

Total final enrolment
20

Key exclusion criteria
1. Participants with compromised conditions
2. Participants exhibiting signs and symptoms indicative of pulp necrosis
3. Participants with a history of spontaneous pain in their second primary molars
4. Participants with a history of nocturnal pain in their second primary molars

Date of first enrolment
13/01/2024

Date of final enrolment
20/01/2024

Locations

Countries of recruitment
Syria

Study participating centre
Damascus University
Mazzeh
Damascus
Syria
-

Sponsor information

Organisation
Damascus University

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Sponsor type
University/education

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https://ror.org/03m098d13

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
01/05/2025

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