

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

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<b>Registration date</b> 23/01/2025	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 23/01/2025	<b>Condition category</b> Oral Health	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## 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?  
Dr Mawia Karkoutly, mawia95.karkoutly@damascusuniversity.edu.sy,  
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## Contact information

**Type(s)**  
Public, Scientific, Principal investigator

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## Additional identifiers

**Clinical Trials Information System (CTIS)**  
Nil known

**Protocol serial number**  
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

### **Study type(s)**

Treatment

### **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(s)**

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

### **Key secondary outcome(s)**

There are no secondary outcome measures

### **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

### **Healthy volunteers allowed**

No

### **Age group**

Child

### **Lower age limit**

5 years

### **Upper age limit**

10 years

**Sex**

All

**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

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## **Sponsor information**

**Organisation**

Damascus University

**ROR**

<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

**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