ISRCTN15908457 https://doi.org/10.1186/ISRCTN15908457

Pulpotomy in primary molars utilizing 2.25% sodium hypochlorite gel

Submission date	**Recruitment status**	[_] Prospectively registered
22/07/2024	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
22/07/2024	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
03/07/2025	Oral Health	

Plain English summary of protocol

Background and study aims
A pulpotomy is a way to remove infected pulp tissue within a tooth to save the tooth. Zinc oxide-eugenol (ZOE) is widely applied as base material following pulpotomy. However, ZOE causes mild pulp inflammation when applied directly to the exposed pulp tissue with a lack of dentin bridge formation. Mineral trioxide aggregate (MTA) is a biocompatible cement that stimulates dentine formation. Given its antimicrobial effects, NaOCl gel is expected to induce healing and improve pulpotomy treatment outcomes. Therefore, this study aimed to evaluate pulpotomy in human primary molars using NaOCl gel followed by white MTA (WMTA) as a base material.

Who can participate?
Histological study: patients aged 8-10 years requiring serial extraction and pulpotomy of first primary molars
Clinical and radiographical study: patients aged 5-10 years requiring pulpotomy of second primary molars

What does the study involve?
Histological study:
Participants were randomly allocated into two groups according to the pulpotomy agent used:
Group 1 (NaOCl gel): Following hemostasis, teeth were pulpotomized using NaOCl gel and then WMTA paste was applied as a dressing material.
Group 2 (control): Following hemostasis, WMTA paste was applied as a dressing material.
Each group was subdivided into three sub-groups according to the time planned for serial extraction:
Sub-group I: 7 days
Sub-group II: 30 days
Sub-group III: 90 days

Clinical and radiographical study:
Participants were randomly allocated into two groups according to the pulpotomy agent used:
Group 1 (NaOCl gel)
Group 2 (control)
Follow-up intervals were scheduled after 3, 6, and 12 months.

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

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

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

Who is funding the study?
Damascus University (Syria)

Who is the main contact?
Dr Mawia Karkoutly, mawia95.karkoutly@damascusuniversity.edu.sy

Contact information

Type(s)
Public, Scientific, Principal Investigator

Contact name
Dr Mawia Karkoutly

ORCID ID
https://orcid.org/0000-0003-0227-1560

Contact details
Al Mazzeh Street
Damascus
Syria
-
+963 (0)992 647 528
mawia95.karkoutly@damascusuniversity.edu.sy

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Treatment outcomes of pulpotomy in primary molars utilizing 2.25% sodium hypochlorite gel as a medicament: a randomized controlled trial

Study objectives
The null hypothesis is that using 2.25% sodium hypochlorite gel as a medicament in human primary molars pulpotomy will not improve the treatment outcomes of white mineral trioxide aggregate (WMTA).

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 10/01/2023, The Biomedical Research Ethics Committee (Mezzeh highway, Damascus, -, Syria; +963 (11) 33923223; dean.dent@damascusuniversity.edu.sy), ref: 226/2023

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

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
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

Interventions
Histological study:
A randomized, triple-blinded, single-center, split-mouth, active-controlled clinical trial with two arms. Two pediatric experienced pediatric dentists (ICC >0.8) recruited 24 patients out of 31 patients who were referred to the Department of Pediatric Dentistry. Recruited patients with 48 first primary molars indicated for pulpotomy were randomly allocated into two groups (n = 24) according to the pulpotomy agent used:
Group 1 (NaOCl gel): Following hemostasis, teeth were pulpotomized utilizing 2.25% NaOCl gel (LET'S CLEAN Concentrated Chlorine, DTIC®, Damascus, Syria) and then WMTA paste (Rootdent, TehnoDent Co., Belgorod, Russia) was applied as a dressing material.
Group 2 (control): Following hemostasis, WMTA paste was applied as a dressing material.

Each group was subdivided into three sub-groups (n = 8) according to the time planned for serial extraction:
Sub-group I: 7 days.
Sub-group II: 30 days.
Sub-group III: 90 days.

A diagnostic periapical radiograph was taken by means of an intraoral periapical sensor (i-sensor, Guilin Woodpecker Medical Instrument Co., LTD., Guilin, China). After achieving adequate anesthesia and isolation, the caries was removed and the coronal pulpotomy was performed. Hemorrhage was controlled using a sterile cotton pellet soaked in normal saline (SODIUM CHLORIDE 0.9% MIAMED, Miamed Pharmaceutical Industry, Damascus, Syria) and compressed over the pulpal stump for 5 m. Following hemostasis, in the NaOCl gel group, a sterile cotton pellet was soaked in 2.25% NaOCl gel and compressed in the pulpal chamber for 3 min and then the cavity was filled with WMTA paste. In the control group, the pulpal chamber was filled with MTA paste immediately after achieving hemostasis. The powder WMTA was mixed with distilled water in a 3:1 powder-to-liquid ratio. The extracted samples were immediately restored for fixation in 10% buffered formalin solution (10% Neutral Buffered Formalin, Thomas Scientific LLC, New Jersey, United States) for 48 h. Samples were decalcified by an aqueous solution of 22.5 % formic acid and 10 % sodium citrate, Morse's solution (Morse Solution, FUJIFILM Wako Pure Chemical Co., Hong Kong, China). Samples were embedded in paraffin wax block (Clear Paraffin Block, EverBio Technology INC., New Taipei City, Taiwan), and then cut into 5 μm thick longitudinal sections by means of a semi-motorized rotary microtome (Leica RM2145 Microtome, GMI, New Jersey, United States). Sections were stained utilizing hematoxylin and eosin staining (H&E Staining Kit, Abcam, England, United Kingdom), and then evaluated at 400× magnification by two blinded outcome assessors (ICC > 0.8) utilizing a light microscope (Leica Microscope DM2500, Leica, Hesse, Germany).

Clinical and radiographical study:
A randomized, triple-blinded, single-center, split-mouth, active-controlled clinical trial with two arms. Two pediatric experienced pediatric dentists (ICC >0.8) recruited 20 patients out of 26 patients who were referred to the Department of Pediatric Dentistry. Recruited patients with 40 first primary molars indicated for pulpotomy were randomly allocated into two groups (n = 20) according to the pulpotomy agent used:
Group 1 (NaOCl gel)
Group 2 (control)
The treatment procedure was conducted as explained previously. Follow-up intervals were scheduled after 3, 6, and 12 months.

Method of randomisation:
A simple randomization method by flipping a coin.

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

The following primary outcomes will be measured using clinical evaluation after 3, 6, and 12 months:
1. Spontaneous pain
2. Pain on percussion
3. Tooth mobility
4. Abscess
5. Fistula
6. Exfoliation of the treated tooth

The following primary outcomes will be measured using radiographical evaluation after 3, 6, and 12 months:
1. Furcal radiolucency
2. Internal root resorption
3. External root resorption
4. Widening of the periodontal ligament
5. Canal obliteration
6. Dentin bridge formation

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
05/01/2023

Completion date
02/06/2024

Eligibility

Key inclusion criteria
Histological study:
Cooperative patients aged 8-10 years requiring serial extraction and pulpotomy of first primary molars

Clinical and radiographical study:
Cooperative patients aged 5-10 years requiring pulpotomy of 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
44

Total final enrolment
44

Key exclusion criteria
Histological study:
Compromised patients or patients with signs and symptoms of pulp necrosis or spontaneous and /or nocturnal pain history in first primary molars

Clinical and radiographical study:
Compromised patients or patients with signs and symptoms of pulp necrosis or spontaneous and /or nocturnal pain history in second primary molars

Date of first enrolment
04/02/2023

Date of final enrolment
02/05/2023

Locations

Countries of recruitment
Syria

Study participating centre
Damascus University
Department of Pediatric Dentistry
Faculty of Dentistry
Al Mazzeh Street
Damascus
Syria
-

Sponsor information

Organisation
Damascus University

Sponsor details
Al Mazzeh Street
Damascus

Syria
-
+963 (0)992647528
info@damascusuniversity.edu.sy

Sponsor type
University/education

Website
https://www.damascusuniversity.edu.sy/

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

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

Intention to publish date
01/11/2024

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?
Results article		02/07/2025	03/07/2025	Yes	No