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Comparison of two minimally invasive methods for removing tooth decay in children with molar–incisor hypomineralization

Submission date 08/10/2025	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 08/10/2025	**Overall study status** Completed	
Last Edited 08/10/2025	**Condition category** Oral Health	

Plain English summary of protocol

Background and study aims
Some children have a condition called molar–incisor hypomineralization (MIH), which makes the enamel on their first permanent molars weak and more likely to develop cavities. These teeth can be sensitive and painful, and dental treatment can be uncomfortable or scary for affected children. This study is looking at three different ways to gently remove tooth decay in children with MIH, to find out which method works best and feels most comfortable.

Who can participate?
Children aged 6 to 10 years who have severely affected molars due to MIH, are generally healthy, and are able to cooperate during dental treatment can take part in the study.

What does the study involve?
Children will receive treatment for their decayed molars using one of three methods:
1. A gel called BRIX-3000® that uses an enzyme to soften the decay.
2. A chemical gel made with sodium hypochlorite.
3. The traditional method using a dental drill.
All treatments are done with a rubber dam (a protective sheet) to keep the area dry, and the tooth is filled with a child-friendly material afterwards. The study will look at how well each method removes decay, how much discomfort the child feels, how long the treatment takes, and whether extra numbing is needed.

What are the possible benefits and risks of participating?
Children may benefit from receiving high-quality dental care and having their tooth decay treated in a gentle way. There may be some discomfort during treatment, but the study aims to find the least painful method. All procedures are carried out by trained professionals with safety in mind.

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

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

Who is funding the study?
Damascus University (Syria)

Who is the main contact?
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Additional identifiers

Protocol serial number
UDDS-4150-23092024/SRC-1145

Study information

Scientific Title
A randomized controlled clinical trial comparing the efficacy, treatment time, and patient-reported pain perception of BRIX-3000 and sodium hypochlorite gel for chemo-mechanical caries removal in molars affected by molar–incisor hypomineralization

Acronym
CHEMIH

Study objectives
To provide clinical evidence supporting the selection of a child-friendly, tissue-preserving caries removal method for MIH-affected molars.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 23/09/2024, Biomedical Research Ethics Committee of Damascus University (University Presidency Building, University Campus, Baramkeh 23J89, Damascus, -, Syria; +963 1133923012; president@damasuniv.edu.sy), ref: 4150

Primary study design
Interventional

Study design
Single-center interventional randomized controlled trial

Study type(s)
Treatment, Efficacy

Health condition(s) or problem(s) studied
Severe molar–incisor hypomineralization (MIH) in children, leading to post-eruptive enamel breakdown, hypersensitivity, and carious lesions in first permanent molars

Interventions
1. BRIX-3000® Chemo-Mechanical Caries Removal
Agent: BRIX-3000®
Application: Applied to the carious lesion for 2 minutes according to manufacturer instructions.
Procedure: Carious dentin softened by BRIX-3000® is gently excavated using manual excavators (17W, 19W, Medesy, Italy) with non-cutting back surfaces using rotational motions and light pressure.
Caries detector applied for 10 seconds to confirm removal.
Restoration: Cavities restored with bulk-fill resin composite (Tetric N-Ceram Bulk Fill, Ivoclar Vivadent).

2. Sodium Hypochlorite (NaOCl) 2.4% Gel Chemo-Mechanical Caries Removal
Agent: 2.4% NaOCl gel
Application: Applied to the carious lesion for 2 minutes.
Procedure: Softened carious dentin removed using the same manual excavators technique as

above.
Caries detector applied to ensure complete removal.
Restoration: Same as above (bulk-fill resin composite).

3. Conventional Rotary Instrumentation (Control Group)
Instrument: Round tungsten carbide bur mounted on a slow-speed contra-angle handpiece
Procedure: Carious dentin removed using rotary instrumentation until firm dentin is reached; caries detector applied to confirm removal.
Restoration: Same as above (bulk-fill resin composite).

Participants were randomized using a computer-generated block randomization table (block size = 6). The sequence was prepared by an independent researcher, and allocation concealment was maintained with sequentially numbered, opaque, sealed envelopes, opened only after eligibility confirmation.

Intervention Type
Procedure/Surgery

Primary outcome(s)
The completeness of caries removal will be assessed using the Ericson et al. scoring system by two blinded investigators. The endpoint is achieved when all carious dentin is removed, leaving firm dentin with no soft or infected tissue, confirmed by visual inspection and probing with a sharp dental explorer. Scores range from 0 (complete removal) to 5 (residual caries at base and margins of the cavity and ≥2 walls).

Key secondary outcome(s)
1. Pain will be assessed using the Wong-Baker FACES Pain Rating Scale (child self-report) and the FLACC scale (observer-reported) . Scores range from 0–10, with higher scores indicating greater pain or discomfort
2. Total time required to remove carious dentin will be measured using a digital timer. This will allow comparison of procedure duration among BRIX-3000®, sodium hypochlorite gel, and conventional rotary instrumentation
3. The need for supplemental local anesthesia will be recorded as yes/no, based on patient-reported discomfort or pain during caries removal

Completion date
17/04/2025

Eligibility

Key inclusion criteria
1. Health status: Healthy and cooperative children
2. Diagnosis: Presence of first permanent molars affected by severe molar–incisor hypomineralization (MIH).
3. Lesion characteristics: Localized enamel opacity with post-eruptive enamel breakdown.
4. Restorable carious lesion on the occlusal surface
5. Radiographic depth not exceeding two-thirds of dentin thickness.
Symptoms: Spontaneous or persistent hypersensitivity affecting function (e.g., brushing or chewing).
6. Pulp status: Teeth must be vital, and without clinical or radiographic signs of pulp necrosis (no fistula, abscess, mobility, periapical lesion, or internal/external root resorption).

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
6 Years

Upper age limit
10 Years

Sex
All

Total final enrolment
72

Key exclusion criteria
1. Presence of other developmental enamel defects, such as amelogenesis imperfecta.
2. Mild MIH in first permanent molars.
3. Teeth with pulpal pathology, including spontaneous or prolonged pain, abscess, fistula, tooth mobility, periapical lesions, or internal/external root resorption.
4. Children with systemic health conditions or behavioral issues that prevent safe dental treatment.
5. Previous restorative treatment on the target tooth.

Date of first enrolment
01/10/2024

Date of final enrolment
15/04/2025

Locations

Countries of recruitment
Syria

Study participating centre
Department of Pediatric Dentistry
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
Contact: Dr. Hasan Alzoubi, dr.hasan.alzoubi.93@gmail.com
Type of data shared: Individual participant data (IPD) including caries removal scores, pain scale scores (Wong-Baker and FLACC), excavation times, and anesthesia requirements.
Availability: Data will be available after publication of the primary results.
Access criteria: Data will be shared for academic, non-commercial research purposes following a formal request.
Consent and ethics: All participants provided informed consent/parental consent. Data will be anonymized before sharing.
Restrictions: No ethical or legal restrictions beyond participant confidentiality.

IPD sharing plan summary

Available on request