

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 08/10/2025	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 08/10/2025	Condition category Oral Health	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

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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Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

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

Study design

Single-center interventional randomized controlled trial

Primary study design

Interventional

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