ISRCTN28596671 https://doi.org/10.1186/ISRCTN28596671

Treating cavities in weak molar teeth of children: a study comparing three gentle filling methods

Submission date 21/03/2025	**Recruitment status** Recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 01/07/2025	**Overall study status** Ongoing	
Last Edited 01/07/2025	**Condition category** Oral Health	

Plain English summary of protocol

Background and study aims
Conventional caries removal utilizing rotary instruments is prevalent in dentistry. However, it has several drawbacks, such as the generation of heat and pressure, which can lead to pulpal damage, excessive tissue removal, anxiety and stress. Children with molar incisor hypomineralisation (MIH) experience greater dental fear and anxiety compared to their peers. Numerous alternative methods have been developed, including lasers, smart burs, chemomechanical caries removal methods, and the atraumatic restorative technique (ART). MIH-affected molar is more susceptible to caries due to the hypomineralized enamel properties, making it more sensitive to thermal and mechanical stimuli. Therefore, the proposed treatment for MIH should be minimally invasive, aiming to protect, restore, and preserve tooth structure. However, there is currently a lack of guidelines regarding treatment options for this condition, so it is essential to find alternatives that are painless and more acceptable to children.

Who can participate?
Children aged 6-10 years old with permanent first molar affected by severe MIH

What does the study involve?
Participants will be randomly divided into three groups to be treated with atraumatic restorative technique (ART), atraumatic restorative technique with chemomechanical caries removal Brix 3000, or silver modified atraumatic restorative technique (SMART). All the teeth will be evaluated clinically and radiographically for up to one year.

What are the possible benefits and risks of participating?
Children with MIH tend to undergo more dental procedures than their healthy peers, which leads to increased anxiety and fear regarding dental care. Consequently, this aspect is crucial in the decision-making process. The ideal treatment may not always be accessible, necessitating a customized strategy that harmonizes minimally invasive methods with sustainable functional and aesthetic results.

Possible risks are postoperative pain and flair-ups that necessitate endodontic treatment.

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

When is the study starting, and how long is it expected to run?
February 2025 to March 2026

Who is funding the study?
Damascus University (Syria)

Who is the primary contact?
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Contact information

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
UDDS-214-29042025/SRC-300

Study information

Scientific Title
Comparison of atraumatic restorative techniques for managing occlusal caries in molars with molar-incisor hypomineralization: a three-arm randomized controlled trial in pediatric patients

Study objectives
This study is designed to assess the hypothesis that silver modified atraumatic restorative technique (SMART) is a painless and more acceptable technique in children with molars affected by severe-molar-incisor hypomineralization (MIH)

Ethics approval required
Ethics approval required

Ethics approval(s)
submitted 17/03/2025, Damascus University (Almazzeh ST, Damascus, 20872, Syria; +963944372202; ep.srd@damascusuniversity.edu.sy), ref: 214

Study design
Single-center interventional single-blinded randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Molar-incisor hypomineralization (MIH) with occlusal caries, post-eruptive enamel breakdown and hypersensitive

Interventions
Permanent molars affected by MIH with occlusal caries, post-eruptive enamel breakdown and hypersensitive from healthy children aged between 6-10 years will be randomly divided into three groups using http://www.randomization.com:
Group A (control): teeth will be treated with an atraumatic restorative technique
Group B (study): teeth will be treated with an atraumatic restorative technique with chemomecanical caries removal brix 3000.
Group C (study): teeth will be treated with silver modified atraumatic restorative technique (SMART)

ART Group A:
The timer is set and the child is videotaped during the procedure to assess the FLACC index by two blinded evaluators. The intervention begins with the removal of carious dentin using hand excavators of multiple sizes, and the excavated caries tissue is removed with a moistened cotton pellet instead of a water-air syringe to avoid pain stimulation. During the procedure, the child is asked about discomfort or pain using age-appropriate terms, such as putting the tooth to sleep, to determine the need for anesthesia. If anesthesia is required, the timer is temporarily suspended until appropriate local anesthesia is achieved. The endpoint of excavation is evaluated by a dental probe, and the cavity is then cleaned and prepared to receive the restoration. The timer is paused, and the pain index is measured using the Wong-Baker scale. Finally, restoration is undertaken using a high-viscosity glass ionomer cement, EQUIA Forte HT Fil® (GC, Leuven, Belgium).

ART with brix3000 Group B:
The timer is set and the child is videotaped during the procedure to assess the FLACC index by two blinded evaluators. Brix 3000 gel is applied in the carious cavity, and after 60 seconds, chemomechanical removal begins using hand excavators of multiple sizes. To remove the excavated caries tissue, a moistened cotton pellet is used instead of a water-air syringe to avoid stimulating pain. During the procedure, the child is asked about discomfort or pain using age-appropriate terms, such as putting the tooth to sleep, to determine the need for anesthesia. If anesthesia is required, the timer is temporarily suspended until appropriate local anesthesia is achieved. Brix 3000 is reapplied as needed in the cavity. The endpoint of excavation is evaluated by a dental probe, and the cavity is cleaned and prepared to receive the restoration. The timer is paused, and the pain index is measured using the Wong-Baker scale. Finally, restoration is undertaken using high-viscosity glass ionomer cement, EQUIA Forte HT Fil® (GC, Leuven, Belgium).

SMART Group C:
The procedure will be conducted in two separate visits, one week apart. During the first visit, silver diamine fluoride (SDF) is applied to the carious lesion. In the second visit, the cavity is restored using high-viscosity glass ionomer cement, EQUIA Forte HT Fil® (GC, Leuven, Belgium).

Intervention Type
Procedure/Surgery

Primary outcome(s)
Clinical evaluation: Patients will be asked to rate their pain at the time of the procedure (baseline) on the Wong-Baker Faces Scale, where children will set their pain levels by choosing a face; 0 = no hurt, 1 = hurts a little bit, 2 = hurts a little more 3 = hurts even more, 4 = hurts a whole lot, and 5 = hurts worst, and FLACC pain scale (Face, Legs, Activity, Cry, Consolability), and the need for anesthesia. Also, they will be recalled after to assess the restoration survival based on ART restoration criteria and to assess the hypersensitivity using the Schiff Cold Air Sensitivity Scale (SCASS) at 3, 6 and 12 months

Key secondary outcome(s))
Radiographical assessment: After restoration is done a control x-ray will be taken to assess the restoration and the pulp condition at baseline, 3, 6, and 12 months after treatment

Completion date
01/05/2026

Eligibility

Key inclusion criteria
1. Cooperative healthy Children aged 6-10 years.
2. At least a permanent first molar affected by severe Molar Incisor Hypomineralisation (MIH) with 3 to 5 caries according to ICDAS-II.
3. The targeted molar has hypersensitivity 2 or 3 according to (SCASS) and 4a or 4b degree according to (MIH-TNI).

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
6 years

Upper age limit
10 years

Sex
All

Key exclusion criteria
1. The presence of another enamel defects such as amelogenesis imperfecta.
2. Silver allergy
3. Mouth sores, ulcerative gingivitis.
4. Irreversible pulpitis.

Date of first enrolment
01/04/2025

Date of final enrolment
01/02/2026

Locations

Countries of recruitment
Syria

Study participating centre
Damascus University
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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 and/or analyzed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Participant information sheet			24/03/2025	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes