ISRCTN54243749 https://doi.org/10.1186/ISRCTN54243749

# Preventive treatment for hypomineralised molars in children

**Submission date**
10/01/2022

**Recruitment status**
No longer recruiting

**Registration date**
13/01/2022

**Overall study status**
Completed

**Last Edited**
23/05/2024

**Condition category**
Oral Health

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

## Plain English summary of protocol

Background and study aims
Molar incisor hypomineralization (MIH) is a tooth enamel defect with different degrees of severity that affects at least 1 out of 4 first permanent molars (back teeth) and is frequently associated with affected permanent incisors (front teeth). MIH-affected teeth have white-creamy and yellow-brown patches that may have decreased hardness and increased roughness compared to normal enamel. As a result, MIH molars may be more prone to enamel and dentin breakdown and tooth decay. Patients with MIH often report hypersensitivity from the affected teeth. This may hinder proper oral hygiene measures on surfaces that are already prone to plaque buildup due to their roughness. Combined, these factors lead to the development of enamel breakdown and tooth decay, ultimately leading to an increased treatment burden.
At this moment, the effectiveness of silver diamine fluoride and MI Varnish in permanent teeth is proven, but there are no clinical studies comparing the effectiveness of these non-invasive treatments in MIH-affected molars. Also, there is a gap in knowledge about which treatments are most effective for enamel breakdown and tooth decay. The aim of this study is to evaluate the preventive effectiveness of silver diamine fluoride in comparison to MI Varnish in children with MIH-affected molars.

Who can participate?
Children aged 6-9 years old with MIH-affected molars

What does the study involve?
The participants' permanent molars will be randomly allocated to one of the two treatments: silver diamine fluoride or MI Varnish applied using a micro applicator brush for at least 1 minute. Then, petroleum gel will be applied to the same molar. Both treatments will be applied and enamel breakdown and tooth decay will be evaluated at the start of the study and after 3, 6 and 9 months.

What are the possible benefits and risks of participating?
Children will receive dietary advice and brushing instructions at the start of the study. Brushing instructions will include toothbrushing three times a day using a conventional toothbrush and toothpaste containing a fluoride concentration of 1,000 ppm or more which will be provided for all participating children at no cost. Furthermore, the patients will be referred to the pediatric

dentistry department at the University of Damascus for those participants with additional dental needs. There are no registered allergic reactions to the used materials, but the researchers will avoid including children who have experienced allergic reactions with either silver or milk products. They will also never use an amount close to the maximum dose of the products to avoid any health effects.

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

When is the study starting and how long is it expected to run for?
February 2021 to December 2022

Who is funding the study?
Damascus University (Syria)

Who is the main contact?
Zuhair Al-Nerabieah
Zuhairmajid@gmail.com

# Contact information

### Type(s)
Public

### Contact name
Dr Zuhair Al-Nerabieah

### ORCID ID
https://orcid.org/0000-0003-1843-1776

### Contact details
Mazzeh Street
PO Box 30621
Damascus
Syria
0000
+963 (0)969960118
zuhairmajid@gmail.com

### Type(s)
Principal investigator

### Contact name
Dr Zuhair Al-Nerabieah

### ORCID ID
https://orcid.org/0000-0003-1843-1776

### Contact details
Mazzeh Street
PO Box 30621

Damascus
Syria
0000
+963 (0)969960118
zuhairmajid@gmail.com

### Type(s)
Scientific

### Contact name
Dr Zuhair Al-Nerabieah

### ORCID ID
https://orcid.org/0000-0003-1843-1776

### Contact details
Mazzeh Street
PO Box 30621
Damascus
Syria
0000
+963 (0)969960118
zuhairmajid@gmail.com

### Type(s)
Scientific

### Contact name
Prof Mayssoon Dashash

### Contact details
Mazzeh Street
Damascus
Syria
0000
+963 (0)966956853
mdashash@yahoo.com

## Additional identifiers

### Protocol serial number
2984

## Study information

### Scientific Title
Evaluation of the preventive efficacy of silver diamine fluoride in comparison to MI varnish in molars affected with molar incisor hypomineralisation in children

### Acronym

MIH

## Study objectives
1. Silver diamine fluoride will prevent dental caries development in molars affected with molar incisor hypomineralisation (MIH) more than MI Varnish
2. Silver diamine fluoride will prevent post-eruptive enamel breakdown in molars affected with MIH more than MI Varnish

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Approved 13/09/2021, ethics scientific committee at Damascus University (Mazzeh Street, PO Box 30621, Damascus, Syria; +963 (11) 339 23223; drsalloum74@hotmail.com), ref: 2984

## Primary study design
Interventional

## Study design
Single-center Interventional double-blinded randomized controlled trial with a split-mouth design

## Study type(s)
Prevention

## Health condition(s) or problem(s) studied
Molar incisor hypomineralisation

## Interventions
Silver diamine fluoride (SDF) and MI Varnish will be applied on two permanent molars with MIH, in a split-mouth design. 100 patients will be included in the study. The teeth will be randomized into two groups according to the dental material.

Randomization units will be as follows: the type of material (SDF/MI Varnish) and (left/right). Each eligible patient will have to draw two times from sealed opaque envelopes. First, to decide which material will be applied first then on which permanent molar this material will be applied on.

Group 1: one drop of silver diamine fluoride (0.2 mg) will be applied on a permanent molar affected with MIH using a micro applicator brush for at least 1 minute. Then, petroleum gel will be applied to the same molar.

Group 2: one drop of MI Varnish (0.2 mg) will be applied on the other permanent molar affected with MIH using a micro applicator brush for at least 1 minute. Then, petroleum gel will be applied to the same molar.

Both materials will be applied at baseline and after 3, 6 and 9 months.

## Intervention Type
Procedure/Surgery

### Primary outcome(s)
1. Dental caries evaluated according to International Caries Detection and Assessment System (ICDAS) criteria and given one of the following scores: 0, sound surface; A, initial stage caries (first visual change in enamel); B, moderate stage caries (localized enamel breakdown or underlying dark shadow); or C, extensive-stage caries (visible cavitation in dentin). Scored after 3, 6, 9 and 12 months from baseline
2. Posteruptive Enamel Breakdown (PEB) scored according to the criteria proposed by Ghanim et al. (2017). Each molar will be given one of the following scores: 0, no visible enamel break down; 2, less than one-third of the tooth is affected; 3, at least one third but less than two-thirds of the tooth are affected; and 4, at least two-thirds of the tooth are affected. Scored after 3, 6, 9 and 12 months from baseline

### Key secondary outcome(s)
Hypomineralised lesion color stability measured using the vita easy shade device at baseline, 6 and 12 months

### Completion date
15/12/2022

## Eligibility

### Key inclusion criteria
1. Patients and parents of the patients who accept to participate and sign the informed consent
2. Healthy children aged between 6 and 9 years, with cooperative behavior, presenting at least 2 MIH-affected molars in the same arch
3. Teeth that are fully erupted

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Child

### Lower age limit
6 Years

### Upper age limit
9 Years

### Sex
All

### Key exclusion criteria
1. Children with ongoing orthodontic treatment
2. Permanent molars affected by dental fluorosis, amelogenesis, or dentinogenesis imperfecta
3. Children with syndromes or developmental disorders
4. MIH-affected molars with clinically visible caries lesions and/or any PEB, restorations, or

sealants
5. MIH-affected molars with the occlusal surface totally or partially covered by a gingival operculum
6. Children who are allergic to silver or milk products

### Date of first enrolment
15/10/2021

### Date of final enrolment
15/10/2022

## Locations

### Countries of recruitment
Syria

### Study participating centre
**Damascus University**
Pediatric Dentistry Department
Faculty of Dentistry
Mazzeh Street
PO Box 30621
Damascus
Syria
0000

## 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 original data, along with the codebook and analysis scripts, will be stored in a non-publicly available repository at Damascus University. The data will consist of csv sheets with the data of the patients and R analysis scripts. The dataset will be called dataset and the dataset generated by the research, including also preprints and technical reports, will be called dataverse. The dataverse corresponding to this investigation will receive a digital object identifier (DOI). The citation has seven components. Five are human-readable: the author(s), title, year, data repository (or distributor), and version number. Two components are machine-readable: the DOI and the universal numeric fingerprint (UNF). The data generated will be de-identified using R's randomizeR package, removing all personal information. The naming convention for the archives will be date in yyyymmdd-version-identifier.extension format. The use of spaces will be avoided, being replaced by -. The original anonymized data will be published in the Mendeley data repository with restricted access once the data cleaning and exploratory analysis stage is completed. The data will be made public at the time of sending the final report to a peer-reviewed journal, with its DOI corresponding to the data associated with the research. The data will be embargoed until the final report is accepted, at which time it will become publicly available. No access restrictions will be applied to the data once the final project report has been accepted.

### IPD sharing plan summary
Stored in publicly available repository

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | | 21/02/2024 | 23/05/2024 | Yes | No |