

Progress Report: Sri Lanka Clinical Trials Registry

SLCTR registration number: SLCTR/2023/020

Scientific title of trial: Sensitivity in teeth affected by molar incisor hypomineralisation (MIH) in Mexican children: a clinical controlled trial

Date of commencement (enrolment of first participant): 03/11/23

Progression: 6 months 1 year 2 years 3 years

At completion

1. Baseline data

Any changes to the trial design/ methodology/ protocol after commencement: Not applicable

Any changes to trial outcomes after commencement: Not applicable

2. Current status

Recruitment status: Recruitment completed

Number assessed for eligibility: 28 participants

Number recruited and allocated/randomized: 28 participants

Number allocated/randomized to each intervention/arm (please edit as relevant):

Arm 1: 8 participants

Arm 2: 5 participants

Arm 3: 7 participants

Arm 4: 8 participants

Losses/exclusions after allocation/randomization (please edit as relevant):

Arm 1: 0 participants

Arm 2: 0 participants

Arm 3: 1 participant

Arm 4: 0 participants

3. Trial output

Date of trial completion (“last patient, last visit”): Follow up continuing

Final sample size: 28 participants

Summary of Interim/Final data (if available):

At this moment we are working on the analysis of preliminary results.

Abstract presentations of results at scientific meetings

Note: please include a URL link or scanned copy of the abstract

Title of Abstract	Full citation (please include authors, date, title of conference and place of presentation, page number of abstract).
An investigation into sensitivity in teeth affected by molar incisor hypomineralisation (MIH) in Mexican children.	<p>Rivera Maria ^{a,b}, Karakowsky Luis ^c, Medina Carlo ^{b,d}, Manton David ^{a,e}</p> <p>^aCentre for Dentistry and Oral Hygiene, University Medical Centre Groningen, University of Groningen, Groningen, The Netherlands; ^bAcademic Area of Dentistry, Autonomous University of Hidalgo State, Pachuca, Mexico; ^cTechnological University of Mexico, Mexico City, Mexico; ^dAdvanced Studies and Research Center in Dentistry “Dr. Keisaburo Miyata”, Autonomous University of the State of Mexico, Toluca, Mexico; ^eAcademic Center for Dentistry Amsterdam (ACTA), University of Amsterdam and Vrije Universiteit Amsterdam, Amsterdam, The Netherlands.</p> <p>3er Global Summit of the International Association of Paediatric Dentistry IADP, Porto, Portugal on November 8-10, 2024.</p> <p>Number of abstract: 185</p>

Publications

Note: please include a URL link or scanned copy of the publication

Title of paper	Full citation (please include authors, title of journal, volume, issue and page numbers, and/or DOI)
	At this moment not applicable

Rivera, Maria

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 Name and signature of Responsible Registrant/Principal Investigator.
 Date: December 2024



An investigation into sensitivity in teeth affected by molar incisor hypomineralisation (MIH) in Mexican children.

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Background: Molar incisor hypomineralisation is a developmental defect of decreased enamel mineral density, involving at least one first permanent molar and frequently, permanent incisors. The defects range from demarcated, white, yellow and/or brown lesions to post-eruptive breakdown, with clinical consequences such as hypersensitivity and poor restorative outcomes.

Objective: To compare the efficacy of combinations of non-invasive interventions to reduce hypersensitivity in Mexican children with MIH.

Methods: This randomized controlled trial was carried out in 27 participants from 6 to 13 years-of-age with self-reported hypersensitivity. Under the MIH-criteria of the European Academy of Pediatric Dentistry, a dentist performed oral examinations to detect the degree-of-sensitivity using VAS and SCASS tests at baseline, 4, 8, 12 and 26 weeks. Four intervention groups were included: A) Glass ionomer sealant (GIS) and professional topical application of 5% sodium fluoride varnish with CPP-ACP (FV), B) GIS and topical tooth crème with 10% CPP-ACP (TC), C) GIS, FV and TC, D) FV and TC.

Results: Average age was 8.77 ± 1.76 , 59% were female. The mean number of molars with sensitivity was 1 ± 0.26 . Group B at the 4 weeks follow up showed in all the participants a “minor improvement” from VAS and at the 26 weeks follow up showed a “no response” from SCASS and “minor improvement” from VAS. Group C at the 4 weeks follow up in 60% of the participants a “no response” from SCASS and at 26 weeks a “major improvement” from VAS.

Conclusions: The most effective combination of non-invasive treatments to decrease hypersensitivity in children with MIH for short term (one month) was Glass ionomer sealant + tooth mouse and for long term (6 months) were Glass ionomer sealant + tooth mouse and Glass ionomer sealant + fluoride varnish + tooth mouse, however, all groups showed less than 80% effectiveness at 26 weeks.