Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparative study of the results of silver-modified atraumatic restorative treatment (SMART) and preventive resin restoration (PRR) in hypomineralized molars (MIH) with early carious lesions: a randomized clinical trial

Protocol summary

Study aim
Effectiveness of two techniques (silver-modified atraumatic restorative treatment - SMART and Preventive Resin Restoration - PRR) in terms of marginal fit, retention, recurrent caries, and marginal discoloration initially and then at 1 and 6 months post-treatment using the Modified United States Public Health Service (MUSPHS) scale.

Design
A split-mouth clinical trial was conducted on 28 children aged 6 to 13 years with at least two primary molars affected by MIH and in need of SMART and PRR treatments. Randomization was performed using a random number table; however, Without blinding

Settings and conduct
Treatment will be carried out in the pediatric department of Isfahan Dental School. Each tooth is classified into one of the two following groups. In the PRR group, the decayed parts are first removed, and then the tooth is immediately and in the same session restored with composite. In the SMART group, SDF is applied to the occlusal pits of the tooth first, which stops and changes the color of the decayed spots, and then, to increase the stop of decay and reduce color change, the tooth is restored with Glass Ionomer one week later.

Participants/Inclusion and exclusion criteria
Admission Criteria: Children aged 6 to 13 with at least two fully erupted permanent first molars and MIH with a treatment need index of 1 and 3 Dental caries with code 1 or 2 according to the International Caries Detection and Assessment System (ICDAS II) Absence of any systemic disease (ASA I) Discharge Criteria: Ongoing orthodontic treatment Lack of cooperation for dental procedures Molars with existing repairs, fluorosis, or dental abnormalities due to specific syndromes Presence of pulp involvement symptoms

Intervention groups
SMART and PRR intervention groups

Main outcome variables
Marginal fit, adhesive retention, recurrent caries and marginal discoloration

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250209064689N2**
Registration date: **2026-06-11, 1405/03/21**
Registration timing: **registered_while_recruiting**

Last update: **2026-06-11, 1405/03/21**
Update count: **0**

Registration date
2026-06-11, 1405/03/21

Registrant information

Name
narjes amrollahi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2026-05-21, 1405/02/31

Expected recruitment end date
2026-06-19, 1405/03/29
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparative study of the results of silver-modified atraumatic restorative treatment (SMART) and preventive resin restoration (PRR) in hypomineralized molars (MIH) with early carious lesions: a randomized clinical trial

Public title
Evaluation of the results of silver-modified atraumatic restorative treatment (SMART) compared with conventional preventive resin restoration (PRR) in hypomineralized molars (MIH) with early carious lesions: a randomized clinical trial
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Children aged 6 to 13 years with at least two fully erupted permanent first molars and MIH with treatment need score of 1 and 3 (based on European Academy of Paediatric Dentistry (EAPD) criteria) Dental caries with code 1 or 2 according to the International Caries Detection and Assessment System (ICDAS II) Absence of any systemic disease (ASA I)
Exclusion criteria:
Age
From **6 years** old to **13 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **28**
More than 1 sample in each individual
Number of samples in each individual: **2**
This study will be conducted on 28 children with at least two primary molars affected by MIH.
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization will be performed using a random number table and maintained in sealed envelopes by the study supervisor.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences
Street address
Faculty of Dentistry, Isfahan University of Medical Sciences, Hezar Jerib Ave.
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Province
Isfehan
Postal code
8174673461
Approval date
2026-01-13, 1404/10/23
Ethics committee reference number
IR.MUI.DHMT.REC.1404.191

Health conditions studied

1

Description of health condition studied
Molar-Incisor Hypomineralization
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Marginal fit of the repairing material used based on the modified clinical ranking system of the United States Public Health Service (MUSPHS)
Timepoint
Initially and subsequently in the months of 1 and 6 after treatment
Method of measurement
Modified Clinical Ranking System of the U.S. Public Health Service (MUSPHS)

2

Description
Retention of the repairing material used based on the modified clinical ranking system of the United States Public Health Service (MUSPHS)
Timepoint
Initially and subsequently in the months of 1 and 6 after treatment
Method of measurement
Modified Clinical Ranking System of the U.S. Public Health Service (MUSPHS)

3

Description
recurrent caries of the repairing material used based on the modified clinical ranking system of the United States Public Health Service (MUSPHS)
Timepoint
Initially and subsequently in the months of 1 and 6 after treatment
Method of measurement
Modified Clinical Ranking System of the U.S. Public Health Service (MUSPHS)

4

Description
marginal discoloration of the repairing material used based on the modified clinical ranking system of the United States Public Health Service (MUSPHS)
Timepoint
Initially and subsequently in the months of 1 and 6 after treatment
Method of measurement
Modified Clinical Ranking System of the U.S. Public Health Service (MUSPHS)

Secondary outcomes

empty

Intervention groups

1

Description
First intervention group: PRR technique, where initially, surface careis are removed using a small, pear-shaped or rounded end burr under high-speed handpiece cooling with continuous water. The pit and fissures are etched for 20 seconds with 37% phosphoric acid gel (Vococid, Voco, Cuxhaven, Germany) and then rinsed with water, dried, and bonded (Voco, Cuxhaven, Germany) applied, and the tooth is cured for 20 seconds. Finally, the prepared cavity is restored and cured with composite flow (Grandio Shade A2, Voco, Cuxhaven, Germany).
Category
Treatment - Devices

2

Description
Second intervention group: SMART technique, where SDF 38% (Cariestop, Biodinamica Quimica E Farmaceutica, Ibipora, Parana, Brazil) is applied as follows: SDF vial is applied to the entire surface of the tooth using a brush. The tooth is dried with cotton balls and then, to minimize the risk of color change, GIC (Riva Light Cure HV, SDI, Bayswater, Australia) is injected into the pits and fissures one week later and cured for 20 seconds. Finally, excess material is quickly removed and the occlusion is examined and adjusted.
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Children's Department, Faculty of Dentistry, Isfahan University of Medical Sciences
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Nayereh Ahmadi
Position
Pediatric Dentistry Resident
Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All data potentially can be shared after de-identifying individuals
When the data will become available and for how long
The start of the access period is one month after the results are published.
To whom data/document is available
Researchers employed in academic and scientific institutions
Under which criteria data/document could be used
For use in related research and healthcare services
From where data/document is obtainable
N.ahmadi3731@gmail.com
What processes are involved for a request to access data/document
After requesting via email, the necessary reviews will be conducted and the research-related files will be made available to him.
Comments