

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 2026

comparison of the effectiveness of silver diamine fluoride with fluoride varnish in arresting proximal caries of deciduous molars

Protocol summary

Study aim

determine the effect of silver diamine fluoride(SDF) on active proximal caries lesions of primary molar teeth

Design

A randomized clinical trial with a split-mouth design, have a control group, double-blind

Settings and conduct

This study include 100 interproximal carious lesions in 50 patients treat with SDF and varnish fluoride in private pediatric office. 48 hours before the interventions, elastic separators are used to create sufficient access in the proximal areas. Bitewing radiographs and ICCMS™ radiographic scoring criteria and ICDAS scoring criteria are used to assess caries depth in primary teeth at baseline and then at 6-month follow-up. If the comparison of the baseline and 6-month follow-up, show lack of progression, that means caries are considered stopped, otherwise considered advanced and the tooth must be repaired. The researcher and the patient are blinded to the study groups.

Participants/Inclusion and exclusion criteria

Children 3 to 6 years old with at least one untreated proximal caries lesion on the first or second deciduous molars in every side of jaw Based on clinical examinations and bitewing radiographs, the caries is limited to the outer third of the dentin Exit criteria: distinctive systemic disease, Reluctance of the child or parents, Sensitivity to silver or other heavy metal ions, Existence of gingival ulcers or lesions around the mouth, Evidence of pulp involvement

Intervention groups

SDF: After isolation, 30% SDF is applied to the area with a fine microbrush and remains in place for 3 minutes. additions are then cleaned. Fluoride varnish: After isolation, 5% sodium fluoride is applied to all surfaces of the target tooth.

Main outcome variables

arrest decay

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220425054647N1**

Registration date: **2022-09-24, 1401/07/02**

Registration timing: **registered_while_recruiting**

Last update: **2022-09-24, 1401/07/02**

Update count: **0**

Registration date

2022-09-24, 1401/07/02

Registrant information

Name

Afsoon Motallebi

Name of organization / entity

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-23, 1401/07/01

Expected recruitment end date

2022-11-22, 1401/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparison of the effectiveness of silver diamine fluoride with fluoride varnish in arresting proximal caries of deciduous molars Public title effect of silver diamine fluoride in arresting proximal caries of deciduous molars Purpose Treatment Inclusion/Exclusion criteria Inclusion criteria: children have at least one untreated proximal caries lesion on the first or second deciduous molars in every side of jaw(split mouth) Based on clinical examinations and bite-wing radiographs, caries is limited to external one-third of the dentin. children between 3 to 6 years old Exclusion criteria: Children with systemic diseases Children who themselves or their parents do not want to intervene Sensitivity to silver or other heavy metal ions Existence of gingival ulcers or lesions around the mouth Evidence of pulp involvement (radiographic evidence or clinical signs such as abscess) Age From 3 years old to 6 years old Gender Both Phase N/A Groups that have been masked • Participant • Investigator • Outcome assessor • Data analyser Sample size Target sample size: 100 More than 1 sample in each individual Number of samples in each individual: 2 100 teeth, from 50 healthy children aged 3 to 6 years with at least one untreated proximal caries of first or second mandibular molars on each side Randomization (investigator's opinion) Randomized Randomization description simple randomization two envelope with number 1 and 2 are prepared and every participant choose one envelope randomly number 1 (SDF on the right tooth and varnish flouride on the loft) number 2 (varnish flouride on the right tooth and SDF on the left) Blinding (investigator's opinion) Double blinded Blinding description Both intervention groups are performed on one person (split mouth) who is not aware of difference of the intervention group. Clinical examinations and radiographs are performed by one of the researchers who is blind to the study groups. Placebo Not used Assignment Parallel	Other design features In this study, the design will be split-mouth Secondary Ids empty Ethics committees <u>1</u> Ethics committee Name of ethics committee Ethics committee of North Khorasan University of Medical Sciences Street address bojnourd dental university City bojnourd Province North Khorasan Postal code 9417694735 Approval date 2022-08-28, 1401/06/06 Ethics committee reference number IR.NKUMS.REC.1401.040 Health conditions studied <u>1</u> Description of health condition studied dental caries ICD-10 code K02.6 ICD-10 code description Dental caries on smooth surface Primary outcomes <u>1</u> Description tooth decay score based on ICDAS and ICCMS indices Timepoint Indices code at the beginning of the study and 6 months later Method of measurement Clinical and radiographic examination based on indices: International Caries Detection and Assessment System (ICDAS) , The International Caries Classification and Management System (ICCMS) Secondary outcomes empty Intervention groups
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Description

Intervention group: applying one drop of 30% silver diamine fluoride (Biodinamica, Brazil) with fine microbrush on the targeted surface area and waiting for 3 minute then clear excess

Category

Prevention

2

Description

Control group: applying 5% sodium fluoride varnish (Centrix, America) with fine brush on the targeted surface area.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

pediatric dental office

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bojnourd University of Medical Sciences

Full name of responsible person

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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

Bojnourd 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

Bojnourd University of Medical Sciences

Full name of responsible person

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Position

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Latest degree

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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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Participants data file, study protocol, statistical analysis map, informed consent form, clinical study report

When the data will become available and for how long

one year

To whom data/document is available

Applicants

Under which criteria data/document could be used

Continue research

From where data/document is obtainable

Principal investigator

What processes are involved for a request to access data/document

Submit request then review

Comments