Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 Oct 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
Iran (Islamic Republic of)

Phone
+98 58 3225 9729

Email address
motalebia@yahoo.com

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

1

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

1

Description of health condition studied
dental caries

ICD-10 code
K02.6

ICD-10 code description
Dental caries on smooth surface

Primary outcomes

1

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) و The International Caries Classification and Management System (ICCMS)

Secondary outcomes

empty

Intervention groups

1

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 fuoride 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
Afsoon Motallebi
Street address
5th Floor, Farhad building, 26 Eastern Taleghani, Shahid square
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Bojnourd University of Medical Sciences
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Phone
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Email
iran6289@gmail.com
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
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Position
Assistant professor
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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