Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Influence of silver diamine fluoride application with and without light curing on arresting early childhood caries and effect on oral health related quality of life: randomized clinical control

Protocol summary

Study aim

Despite increasing attention to preventive dentistry, the prevalence of ECC i is still high. Many of caries remain untreated at this young age because of uncooperative child and lack of treatment facilities for treatment under general anesthesia. These untreated caries can affect the quality of life of the child and his parents. SDF is known to be effective in arresting dentinal caries in deciduous teeth. In this study, the effect of SDF application with different protocols on arresting the decay process and also the effect of this treatment on the oral health related quality of life in children and their parents will be measured.

Design

Random clinical trial with parallel, double-blind groups. A list of random numbers will be used for randomization.

Settings and conduct

Children are randomly divided into two groups using a list of random numbers. In each group, for each individual, two eligible molar teeth are treated with SDF.In the first group, the SDF application time will be 1 minute and in the second group, 30 seconds. One tooth per person is randomly irradiated with light cure for 40 seconds after SDF application. oral health status, arrest of dental caries and quality of life are assessed at each follow-up . arrest of caries by tactile examination is assessed by dentist who is blinded about the group of dental treatment.

Participants/Inclusion and exclusion criteria

Children between 2-4 years of age with active dentin caries (ICDAS 6) without symptomatic involvement or pulp necrosis without significant systemic disease (ASA I and II) who are unable to cooperate with routine dental treatment

Intervention groups

One side of the patient's mouth will be exposed to light cure after SDF application and the other side will only be treated with SDF.

Main outcome variables

arrest of early childhood caries in children, oral health related quality of life .

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170305032881N2**
Registration date: **2022-04-19, 1401/01/30**
Registration timing: **retrospective**

Last update: **2022-04-19, 1401/01/30**
Update count: **0**

Registration date

2022-04-19, 1401/01/30

Registrant information

Name
Zahra Mohammadzadeh
Name of organization / entity
Mashhad dental school
Country
Iran (Islamic Republic of)
Phone
+98 51 3662 9015
Email address
mohammadzadehz@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-22, 1400/09/01

Expected recruitment end date

2022-02-20, 1400/12/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Influence of silver diamine fluoride application with and without light curing on arresting early childhood caries and effect on oral health related quality of life: randomized clinical control

Public title
effect of silver diamine fluoride with or without the use of light cure
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Children between 2-4 years without significant systemic disease (ASA I and II) who are unable to cooperate in routine dental treatment. Lack of sensitivity to SDF ingredients Consent of parents / caregivers to their child's participation in the study Presence of at least 2 teeth / 1 pair of deciduous molars with dentin caries lesion (ICDAS 6) active without signs of involvement or pulp necrosis child cooperation for SDF application and parents' desire to follow the next follow-ups and follow the oral health instructions
Exclusion criteria:
Severely non-cooperative patients for whom application of SDF is not possible. Children with sensitivity to SDF content Children with deep exposed caries
Age
From **2 years** old to **4 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **30**
More than 1 sample in each individual
Number of samples in each individual: **2**
a paired of caries molar teeth
Randomization (investigator's opinion)
Randomized
Randomization description
A list of random numbers will be created using the WWW.randomizer.org site. A simple randomization method will be used dental assistant who is not participating in the study will have a list of random numbers and will determine the side of the light cure treatment.
Blinding (investigator's opinion)
Double blinded
Blinding description
A dental assistant who does not participate in the study will have a list of random numbers and will determine the side of the light cure treatment .and Will register as a code. IN follow-up sessions, the evaluator will be blinded about which side belongs to which group.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Mashhad University of Medical Sciences
Street address
Department of Pediatric Dentistry, Faculty of Dentistry, Mashhad University of Medical Sciences,Vakil Abad Blvd, Mashhad,Iran
City
Mashhad
Province
Razavi Khorasan
Postal code
9177948959
Approval date
2021-12-05, 1400/09/14
Ethics committee reference number
IR.MUMS.DENTISTRY.REC.1400.121

Health conditions studied

1

Description of health condition studied
early childhood caries
ICD-10 code
K02.1
ICD-10 code description
پوسیدگی گسترده دندانهای شیری که به عاج رسیده اما درگیری پالپ ایجاد نکرده است

Primary outcomes

1

Description
caries arrest
Timepoint
1 month,3 months,6 months
Method of measurement
visual and tactile assessment

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: SDF with light curing on caries primary molar
Category
Treatment - Drugs

2

Description
Control group: SDF without light curing on caries primary molar
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Faculty of Dentistry ,Mashhad university of Medical Sciences
Full name of responsible person
Zahra Mohammadzadeh
Street address
Department of pediatric dentistry,Faculty of Dentistry,Mashhad University of Medical Sciences,Vakil Abad Blvd,Mashhad,Iran.
City
Mashhad
Province
Razavi Khorasan
Postal code
9177948959
Phone
+98 51 3882 9500
Email
mohammadzadehz@mums.ac.ir
Web page address

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr Hossein Bagheri
Street address
Department of pediatric dentistry,Faculty of Dentistry,Mashhad University of Medical Sciences,Vakil Abad Blvd,Mashhad,Iran.
City
Mashhad
Province
Razavi Khorasan
Postal code
9177948959
Phone
+98 51 3882 9500
Email
mohammadzadehz@mums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Dr Zahra Mohammadzadeh
Position
Assisstent Professor
Latest degree
Specialist
Other areas of specialty/work
Dentistry
Street address
Department of pediatric dentistry,Faculty of Dentistry,Mashhad University of Medical Sciences,Vakil Abad Blvd,Mashhad,Iran.
City
Mashhad
Province
Razavi Khorasan
Postal code
9177948959
Phone
+98 51 3882 9500
Email
mohammadzadehz@mums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Dr Zahra Mohammadzadeh
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Dentistry
Street address
Department of pediatric dentistry,Faculty of Dentistry,Mashhad University of Medical Sciences,Vakil Abad Blvd,Mashhad,Iran.
City
Mashhad
Province
Razavi Khorasan
Postal code
9177948959
Phone
+98 51 3882 9500
Email
mohammadzadehz@mums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr Zahra Mohammadzadeh
Position
assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Dentistry
Street address
Department of pediatric dentistry,Faculty of Dentistry,Mashhad University of Medical Sciences,Vakil Abad Blvd,Mashhad,Iran
City
Mashhad
Province
Razavi Khorasan
Postal code
9177948959
Phone
+98 51 3882 9501
Email
mohammadzadehz@mums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
No - There is not 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
comparison the arrest of dental caries
When the data will become available and for how long
6 months after paper publication
To whom data/document is available
academic researcher
Under which criteria data/document could be used
At the reasonable request of researchers, raw study information will be provided to them
From where data/document is obtainable
By sending an email to the corresponding author
What processes are involved for a request to access data/document
as soon as possible after sending email
Comments