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Effectiveness of silver fluoride agents to arrest caries in children

Submission date
26/06/2022

Recruitment status
No longer recruiting

Registration date
11/07/2022

Overall study status
Completed

Last Edited
11/07/2022

Condition category
Oral Health

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Dental decay is a major frequent non-communicable form of disease that affects 60-90% children worldwide. More recently, Marcenes et al. reported untreated decay of the permanent teeth as the most prevalent condition world over and untreated decay of deciduous dentition 10th most prevalent condition, in the Global Burden of Disease Study, 2010. Untreated dental caries can adversely affect children's quality of life and result in severe consequences including risk of dental sepsis. A significant association has also been reported between untreated decay and low body mass.
Although, the effectiveness of silver diamine fluoride is proven, but one of the disadvantages of using SDF in the black discoloration. on the other hand, it's well known by now that nano silver doesn't cause this disadvantage, Also, previous studies have used subjective measures to detect the cariostatic efficacy of SDF and NSF. The aim of this study was to evaluate the cariostatic effectiveness of silver diamine fluoride in comparison to nano-silver fluoride in children using Reveal Fluorescence Dental loupes (Designs for Vision, USA).

Who can participate?
Children aged 6-9 years old with untreated cavitated dental caries

What does the study involve?
The participants' primary molars will be randomly allocated to one of the two treatments: silver diamine fluoride or Nano-silver fluoride applied using a micro applicator brush for at least 1 minute. Then, petroleum gel will be applied to the same molar. Participants will be followed up for 3 months

What are the possible benefits and risks of participating?
Children will receive dietary advice and brushing instructions at the start of the study. Brushing instructions will include tooth-brushing three times a day using a conventional toothbrush and toothpaste containing a fluoride concentration of 1,000 ppm or more which will be provided for all participating children at no cost. Furthermore, the patients will be referred to the pediatric dentistry department at the University of Damascus for those participants with additional dental

needs. There are no registered allergic reactions to the used materials, but the researchers will avoid including children who have experienced allergic reactions with either silver. They will also never use an amount close to the maximum dose of the products to avoid any health effects.

Where is the study run from?
Damascus University (Syria)

When is the study starting and how long is it expected to run for?
January 2021 to December 2022

Who is funding the study?
Damascus University (Syria)

Who is the main contact?
Zuhair Al-Nerabieah
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Contact information

Type(s)
Principal investigator

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Additional identifiers

Protocol serial number
4423

Study information

Scientific Title
Detection of the cariostatic efficacy of silver diamine fluoride and nano-silver fluoride using reveal fluorescence dental loupes in children

Acronym
SDF NSG

Study objectives
Silver diamine fluoride will arrest cavitated caries in primary molars more than nano-silver fluoride

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 12/01/2021, Ethics scientific committee at Damascus University (Mazzeh Street, PO Box 30621, Damascus, Syria; +963 (11) 339 23223; drsalloum74@hotmail.com), ref: 4423

Primary study design
Interventional

Study design
Single-center Interventional double-blinded randomized controlled trial with a split-mouth design

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Treatment of cavitated carious lesions in primary molars in children

Interventions
Eligible teeth with cavitated carious lesion in preschool children will be randomly divided into 2 groups:
Silver diamine fluoride, arm 1
Nano-Silver Fluoride biologically synthesized, arm 2
The affected tooth surface will be gently cleaned by a disposable micro-brush applicator for at least 30 seconds and then dried with cotton gauze.
The gingival tissue of the tooth will be protected with petroleum jelly. A new micro-brush applicator will be dipped into one of the agents and 3–4 mg will be applied to the lesion (1 drop treats 3 to 5 teeth). No rinse will be performed and the tooth surface will be covered with petroleum jelly.
Kindergarten teachers will be notified that participants aren't allowed to eat or drink for an hour after the application.
The application of all topical agents will be done by an experienced investigator and the intervention will be delivered in the kindergarten.

Intervention Type
Mixed

Primary outcome(s)
Caries Arrest will be measured using Reveal Fluorescence Dental loupes at (T0) Baseline and re-evaluated at (T1) : 3 weeks after applying topical agents. and (T2): 3 months after applying topical agents

Key secondary outcome(s)

Patient discomfort will be assessed using Wong-Baker Faces scale, It will be assessed immediately after the sequence of treatments have been performed.

Completion date
15/12/2022

Eligibility

Key inclusion criteria
1. Have not received antibiotic therapy in the past month before sampling.
2. Good oral hygiene.
3. Co-operative patients approving the trial.
4. Untreated cavitated active caries lesion with dentin exposed based on the ICDAS II (Code 5: dentin cavity easily visible with the naked eye where the surface of cavity feels soft or leathery on gentle probing)
5. Absence of spontaneous pain; negative sensitivity to percussion

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Sex
All

Key exclusion criteria
1. Children weight less than 15 kg.
2. known sensitivity to silver or other heavy-metal ions
3. presence of any gingival or perioral ulceration or stomatitis or presence of a tooth abscess.

Date of first enrolment
15/12/2021

Date of final enrolment
15/09/2022

Locations

Countries of recruitment
Syria

Study participating centre

Damascus University
Pediatric Dentistry Department
Faculty of Dentistry
Mazzeh Street
PO Box 30621
Damascus
Syria
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Sponsor information

Organisation
Damascus University

ROR
https://ror.org/03m098d13

Funder(s)

Funder type
University/education

Funder Name
Damascus University

Alternative Name(s)
University of Damascus, , DU

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Syria

Results and Publications

Individual participant data (IPD) sharing plan
The original data, along with the codebook and analysis scripts, will be stored in a non-publicly available repository at Damascus University. The data will consist of csv sheets with the data of

the patients and R analysis scripts. The dataset will be called dataset and the dataset generated by the research, including also preprints and technical reports, will be called dataverse. The dataverse corresponding to this investigation will receive a digital object identifier (DOI). The citation has seven components. Five are human-readable: the author(s), title, year, data repository (or distributor), and version number. Two components are machine-readable: the DOI and the universal numeric fingerprint (UNF). The data generated will be de-identified using R's randomizeR package, removing all personal information. The naming convention for the archives will be date in yyyymmdd-version-identifier.extension format. The use of spaces will be avoided, being replaced by -. The original anonymized data will be published in the Mendeley data repository with restricted access once the data cleaning and exploratory analysis stage is completed. The data will be made public at the time of sending the final report to a peer-reviewed journal, with its DOI corresponding to the data associated with the research. The data will be embargoed until the final report is accepted, at which time it will become publicly available. No access restrictions will be applied to the data once the final project report has been accepted.

IPD sharing plan summary

Stored in non-publicly available repository