Clinical trial results:
Prevention and treatment of initial rotcaries among elderly in Skåne.

Summary

EudraCT number	2015-005300-29
Trial protocol	SE
Global end of trial date	19 February 2020

Results information

Result version number	v1 (current)
This version publication date	25 October 2024
First version publication date	25 October 2024
Summary attachment (see zip file)	Effect of a single application of silver diamine fluoride on root caries after 12 months in institutionalised older adults—A randomised clinical trial (Gerodontology - 2022 - Ericson - Effect of a single application of silver diamine fluoride on root caries after 12 months.pdf)

Trial information

Trial identification

Sponsor protocol code	SDF1

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Malmö University
Sponsor organisation address	20506 Malmö, Malmö, Sweden, 20506 Malmö
Public contact	Dan Ericson, Malmö University, Faculty of Odontology, +46 0705432497, dan.ericson@mau.se
Scientific contact	Dan Ericson, Malmö University, Faculty of Odontology, +46 0705432497, dan.ericson@mau.se

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	19 February 2020
Is this the analysis of the primary completion data?	Yes
Primary completion date	19 February 2020
Global end of trial reached?	Yes
Global end of trial date	19 February 2020
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The aim of this randomized, single-blinded, placebo-controlled trial was to evaluate the additive effect of a single annual application of SDF for prevention and treatment of incipient root caries in older adult nursing home residents.

Protection of trial subjects:

The cleaned root surfaces of the included teeth were dried with cotton gauze and a dry field was created using cotton rolls. The adjacent gingiva was protected with petroleum jelly. After mouth rinsing following the first treatment at baseline, the patients were asked to describe their experiences of taste, smell, or other sensations during application. Their responses were recorded, along with the tooth surface color and gingival status.

Study procedures and protocols were scrutinized by the study monitor every six months. After 129 (36%) of the participants had been evaluated (by August 2018), independent data and safety monitoring were conducted with respect to efficacy and safety, in order to identify any differences between the study groups that would warrant early termination of the trial.

Background therapy:

All participants received routine oral healthcare from the dental care provider, in accordance with risk assessment based on yearly oral health examinations. The individualized procedures included professional tooth cleaning, fluoride varnish application, and dietary and oral hygiene instruction in relation to assessed caries risk. The participants received supervised personal oral hygiene procedures including fluoride toothpaste because they were care-dependent.

Evidence for comparator:

See below

Actual start date of recruitment	09 January 2017
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Sweden: 356
Worldwide total number of subjects	356
EEA total number of subjects	356

Notes:

Subjects enrolled per age group	
In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	0
From 65 to 84 years	92
85 years and over	264

Subject disposition

Recruitment

Recruitment details:

Eligible participants were recruited from January 2017 to October 2018 in nursing homes in Skåne.

Pre-assignment

Screening details:

Eligible individuals were identified during routine dental examination visits. The responsible medical nurse advised whether the individual was able to understand and to make an informed decision to consent to participation. Each received oral and written information about the study.

Period 1

Period 1 title	overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Single blind
Roles blinded	Subject

Blinding implementation details:

Placebo application.

Arms

Are arms mutually exclusive?	Yes
Arm title	Silver diamine fluoride

Arm description:

Application of Silver diamine fluoride

Arm type	Experimental
Investigational medicinal product name	Advantage Arrest Silver Diamine Fluoride 38%, Advantage Arrest, LLC, Redmond, OR 97756, USA, Lot 16 152
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Dental solution
Routes of administration	Dental use

Dosage and administration details:

The cleaned root surfaces of the included teeth were dried with cotton gauze and a dry field was created using cotton rolls. The adjacent gingiva was protected with petroleum jelly. Participants were randomly assigned to receive SDF (Advantage Arrest Silver Diamine Fluoride 38%, Advantage Arrest, LLC, Redmond, OR 97756, USA,
Lot 16 152) or placebo (tap water), applied sparingly on root surfaces with a micro applicator brush and left undisturbed for 1 minute. Participants were then allowed to rinse with water.

Arm title	Placebo

Arm description:

Placebo (tap water)

Arm type	Placebo
Investigational medicinal product name	water
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Dental suspension
Routes of administration	Dental use

Dosage and administration details:

water

Number of subjects in period 1	Silver diamine fluoride	Placebo
Started	174	182
Completed	135	138
Not completed	39	44
Lost to follow-up	39	44

Baseline characteristics

Reporting groups	
Reporting group title	overall trial
Reporting group description:	
Care home residents	

Reporting group values	overall trial	Total	
Number of subjects	356	356	
Age categorical			
Subjects were 70 years and older			
Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	0	0	
From 65-84 years	92	92	
85 years and over	264	264	
Age continuous			
Individuals fulfilling trial 356			
Units: years			
arithmetic mean	88		
standard deviation	± 6.6	-	
Gender categorical			
Units: Subjects			
Female	249	249	
Male	107	107	

End points

End points reporting groups

Reporting group title	Silver diamine fluoride
Reporting group description: Application of Silver diamine fluoride	
Reporting group title	Placebo
Reporting group description: Placebo (tap water)	

Primary: root caries change score

End point title	root caries change score
End point description: The status at surface level was classified as new caries or caries progression (+1), no change (0), or caries regression/inactivation (−1) and the root caries change score is the summation of the individual surface scores within the subject.	
End point type	Primary
End point timeframe: over all study	

End point values	Silver diamine fluoride	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	138	135		
Units: subjects				
Root caries change score +3	1	0		
Root caries change score +2	6	3		
Root caries change score +1	11	10		
Root caries change score 0	110	108		
Root caries change score -1	8	12		
Root caries change score -2	2	2		

Statistical analyses

Statistical analysis title	Root surface status at baseline and after 12 month
Statistical analysis description: Comparison of root change score between SDF and Placebo	
Comparison groups	Silver diamine fluoride v Placebo

Number of subjects included in analysis	273
Analysis specification	Pre-specified
Analysis type	equivalence
P-value	> 0.05
Method	t-test, 2-sided
Parameter estimate	Mean difference (final values)

Adverse events

Adverse events information	
Timeframe for reporting adverse events: At baseline directly after treatment. At 6 month monitor report.	
Assessment type	Non-systematic
Dictionary used	
Dictionary name	SNOMED CT
Dictionary version	240531
Reporting groups	
Reporting group title	Dental hygienist operator
Reporting group description: Dental hygienist delivering treatment	
Reporting group title	Study monitor
Reporting group description: Study monitor	

Serious adverse events	Dental hygienist operator	Study monitor	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 356 (0.00%)	0 / 356 (0.00%)	
number of deaths (all causes)	0	75	
number of deaths resulting from adverse events	0	0	

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	Dental hygienist operator	Study monitor	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	2 / 356 (0.56%)	0 / 356 (0.00%)	
Injury, poisoning and procedural complications			
Gingival erosion			
subjects affected / exposed	2 / 356 (0.56%)	0 / 356 (0.00%)	
occurrences (all)	2	0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported

Online references

http://www.ncbi.nlm.nih.gov/pubmed/36404644