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The effect of MI Varnish™ on the development of tooth decay in 6- and 12-year-old children in Riga, Latvia

Submission date
07/03/2022

Recruitment status
No longer recruiting

Registration date
07/03/2022

Overall study status
Completed

Last Edited
14/08/2023

Condition category
Oral Health

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Tooth decay (dental caries) is damage to a tooth that can happen when decay-causing bacteria in your mouth make acids that attack the tooth's surface, or enamel. This can lead to a small hole in a tooth, called a cavity. If tooth decay is not treated, it can cause pain, infection, and even tooth loss.
Fluoride varnish (FV) is considered safe, well accepted by children, and easily delivered by health practitioners. A therapeutic product combining fluoride and CPP-ACP in a varnish (MI Varnish™; GC corporation, Japan) was developed few years ago demonstrating its caries prevention potential.
The aim of the present study was to investigate the effect of MI Varnish™ on caries increment in 6- and 12-year old children in Riga, Latvia within 36 months.

Who can participate?
6- and 12-year old children, inhabitants of Riga, who visited the Institute for dental treatment.

What does the study involve?
All children were recruited into the study during their regular dental check-ups in a random manner. On meeting the examiner, odd numbers of both age groups were recruited into the Varnish group (6 years old into group 1; 12 years old into group 3), while even numbers were recruited into the control groups (6 years old into group 2; 12 years old into group 4).
Following the baseline caries examination, the treatment groups (group 1 & 3) received the application of MI Varnish™ (5% sodium fluoride GC Corp., Tokyo, Japan), while the control groups (Group 2 & 4) did not have varnish applied.
Groups 1 & 3 had the varnish applied every 3 months for 3 years.
All subjects received general oral hygiene instruction at baseline and at the last visit.

What are the possible benefits and risks of participating?
Benefits: Participants will receive more frequent checkups for dental caries.
Risks: None

Where is the study run from?
Riga Stradins University (Latvia)

When is the study starting and how long is it expected to run for?
December 2015 to March 2020

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Jekaterina Gudkina, jekaterina.gudkina@rsu.lv

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
U1111-1275-4126

Study information

Scientific Title
The effect of MI Varnish™ on dental caries among 6- and 12-year-old children in Riga, Latvia. A 3-year study.

Study objectives
Quarterly application of MI Varnish™ could reduce caries increment in children in Riga, Latvia.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 17/12/2015, RSU Ethics Committee (16 Dzirciema str., Riga, Latvia; +371 67326203; pek@rsu.lv), ref: not provided

Study design
Single-center interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Dental clinic, University/medical school/dental school

Study type(s)
Prevention

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Dental caries development

Interventions
Current interventions, as of 04/04/2022:

All children were recruited into the study during their regular dental check-ups in a random manner as follows. During the visit, children are listed in serial numbers in the order of their arrival time at the reception desk of the RSU Institute of Stomatology. On meeting the examiner, odd numbers of both age groups were recruited into the Varnish group (6 years old into group 1; 12 years old into group 3), while even numbers were recruited into the control groups (6 years old into group 2; 12 years old into group 4).

Following the baseline caries examination, the treatment groups (groups 1 & 3) received the application of MI Varnish™ (5% sodium fluoride GC Corp., Tokyo, Japan), while the control groups (Group 2 & 4) did not have varnish applied. Application of MI varnish was performed in accordance with the manufacturer's instruction. The post-varnish instruction as provided by the manufacturer was given to all children and their parents. Neither the children nor their parents in the Varnish (Groups 1 and 3) were informed about the name of varnish (MI Varnish) used, and the manufacturer's name.

Subsequently, subjects in the treatment groups (group 1 & 3) were recalled every 3 months for re-application of varnish for the 36 months study period. Subjects in the control groups (Group 2

& 4) again received only oral hygiene instruction. Children and their parents were informed about the precise time of attending the dentist by using the mobile telephone number provided at a baseline. At the baseline and 3 monthly MI Varnish re-application visits, teeth were brushed with non-fluoridated professional toothpaste (Zircate Prophy Paste; Dentsply Caulk, Germany) and then MI Varnish™ (GC Corp., Tokyo, Japan) was reapplied on all tooth surfaces.

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Previous interventions:

All children were recruited into the study during their regular dental check-ups in a random manner as follows. During the visit, children are listed in serial numbers in the order of their arrival time at the reception desk of the RSU Institute of Stomatology. On meeting the examiner, odd numbers of both age groups were recruited into the Varnish group (6 years old into group 1; 12 years old into group 3), while even numbers were recruited into the control groups (6 years old into group 2; 12 years old into group 4).

Following the baseline caries examination, the treatment groups (groups 1 & 3) received the application of MI Varnish™ (5% sodium fluoride GC Corp., Tokyo, Japan), while the control groups (Group 2 & 4) did not have varnish applied. Application of MI varnish was performed in accordance with the manufacturer's instruction. The post-varnish instruction as provided by the manufacturer was given to all children and their parents. Neither the children nor their parents in the Varnish (Groups 1 and 3) were informed about the name of varnish (MI Varnish) used, and the manufacturer's name.

Subsequently, subjects in the treatment groups (group 1 & 3) were recalled every 3 months for re-application of varnish and reinforcement of the oral hygiene instructions for the 36 months study period. Subjects in the control groups (Group 2 & 4) again received only oral hygiene instruction. Children and their parents were informed about the precise time of attending the dentist by using the mobile telephone number provided at a baseline. At the baseline and 3 monthly MI Varnish re-application visits, teeth were brushed with non-fluoridated professional toothpaste (Zircate Prophy Paste; Dentsply Caulk, Germany) and then MI Varnish™ (GC Corp., Tokyo, Japan) was reapplied on all tooth surfaces.

Intervention Type
Other

Primary outcome measure
Current primary outcome measure as of 04/04/2022:

Measured at baseline and 36 months:
1. Caries increment measured using the caries assessment criteria of the ICDAS II (https://www.iccms-web.com)
2. Oral hygiene indices measured using the Green-Vermillion oral hygiene index (G-V index)
3. Dietary habits measured using a questionnaire for children and/or their parents about snacking habit, intake of chocolates, carbonated soft or sport drinks during the day, number of tea spoons of sugar (t.s.) per cup of tea, and the number of cups of tea consumed daily

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Previous primary outcome measure:

Measured at baseline and every 3 months for 36 months:
1. Caries increment measured using the caries assessment criteria of the ICDAS II and digital bitewing (BW) X-rays
2. Oral hygiene indices measured using the Green-Vermillion oral hygiene index (G-V index)
3. Dietary habits measured using a questionnaire for children and/or their parents about snacking habit, intake of chocolates, carbonated soft or sport drinks during the day, number of tea spoons of sugar (t.s.) per cup of tea, and the number of cups of tea consumed daily

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
17/12/2015

Completion date
13/03/2020

Eligibility

Key inclusion criteria
Healthy volunteers at the age of 6 and 12 years, living in Riga.

Participant type(s)
Healthy volunteer

Age group
Child

Lower age limit
6 Years

Upper age limit
12 Years

Sex
Both

Target number of participants
A total number of 64 children per group has been estimated to detect a difference between groups, with a two-tailed α of 0.05 and a (1-β) of 0.80, for a comparison of 2 independent means if there was an absolute difference of 5 units outcome measure and standard deviation of 9 units. The drop out was calculated as 25%. Sample size was calculated as follows: Type I error = 5% implies constant 1,96 Type 2 error = 20% implies constant 0,84 N=2*[((1,96+0,84)*SD)/(difference)]2 = 2*(2,8*9/5)2=50,8032~51 N(with drop-out)=1,25* 51 = 63,75 ~ 64 children per each group.

Total final enrolment
260

Key exclusion criteria

1. Children and/or their parents refused to participate in the study
2. The families moved away from Riga
3. Children or parents did not answer the 3 telephone calls confirming their appointments
4. Orthodontic braces
5. General ill-health within the study period

Date of first enrolment
01/02/2016

Date of final enrolment
12/03/2017

Locations

Countries of recruitment
Latvia

Study participating centre
RSU Institue of Stomatology
20, Dzirciema street
Riga
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Sponsor information

Organisation
Riga Stradiņš University

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Sponsor type
University/education

Website
http://www.rsu.lv/eng/

ROR
https://ror.org/03nadks56

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
31/12/2022

Individual participant data (IPD) sharing plan
The datasets generated during and analyzed during the current study will be available upon request from Dr Jekaterina Gudkina (j.gudkina@inbox.lv).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file			07/03/2022	No	No
Abstract results		05/07/2021	04/04/2022	No	No
Participant information sheet	control group		04/04/2022	No	Yes
Participant information sheet	intervention group		04/04/2022	No	Yes
Results article		01/06/2022	24/06/2022	Yes	No
Results article	Effects on different tooth surfaces	07/08/2023	14/08/2023	Yes	No