







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

<b>Submission date</b> 07/03/2022	<b>Recruitment status</b> No longer recruiting	 Retrospectively registered
		 Protocol added
<b>Registration date</b> 07/03/2022	<b>Overall study status</b> Completed	 SAP not yet added
		 Results added
<b>Last Edited</b> 14/08/2023	<b>Condition category</b> Oral Health	 Raw data not yet added
		 Study completed

## Plain English Summary

### 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

**Contact name**  
Dr Jekaterina Gudkina

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## Additional identifiers

**EudraCT/CTIS number**  
Nil known

**IRAS number**

**ClinicalTrials.gov number**  
Nil known

**Protocol/serial number**  
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 hypothesis**

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

## **Condition**

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

### **Overall study end date**

13/03/2020

## **Eligibility**

### **Participant 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  $\alpha$  of 0.05 and a  $(1-\beta)$  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  $N=2*[((1,96+0,84)*SD)/(difference)]^2 = 2*(2,8*9/5)^2=50,8032\sim 51$   $N(\text{with drop-out})=1,25* 51 = 63,75 \sim 64$  children per each group.

### **Total final enrolment**

260

### **Participant 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

**Recruitment start date**

01/02/2016

**Recruitment end date**

12/03/2017

## Locations

**Countries of recruitment**

Latvia

**Study participating centre**

**RSU Institute of Stomatology**

20, Dzirciema street

Riga

Latvia

LV-1010

## Sponsor information

**Organisation**

Riga Stradiņš University

**Sponsor details**

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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?
<a href="#">Protocol file</a>			07/03/2022	No	No
<a href="#">Abstract results</a>		05/07/2021	04/04/2022	No	No
<a href="#">Participant information sheet</a>	control group		04/04/2022	No	Yes
<a href="#">Participant information sheet</a>	intervention group		04/04/2022	No	Yes
<a href="#">Results article</a>		01/06/2022	24/06/2022	Yes	No
<a href="#">Results article</a>	Effects on different tooth surfaces	07/08/2023	14/08/2023	Yes	No