

**PARTICIPANT INFORMATION SHEET AND INFORMED CONSENT FORM
(for children subjects)**

1. **Title of study:** The Pharmacokinetics of Silver Diamine Fluoride in Healthy Children
2. **Reference number of Medical Ethics Committee (Faculty of Dentistry, University of Malaya):** DF CD1914/0065/20157 (P)
3. **Name of investigators and institution:**

(1) Investigator's Name: Dr Lim Siau Peng

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4. **Name of sponsor:** University of Malaya Postgraduate Research Grant

5. Introduction:

Silver diamine fluoride (SDF) is a liquid substance used to help prevent tooth cavities (or caries) from forming or progressing. It's also used to treat tooth sensitivity. SDF is made of silver, fluoride and ammonia. SDF treatment is every 6 to 12 months as necessary.

6. What is the purpose of the study?

To study the body's reaction towards SDF, by assessing the level of silver and fluoride in the urine and hair samples of children receiving SDF treatment.

7. What are the procedures to be followed?

- Your child will be screened prior to the SDF treatment. Dental x-ray, pictures will be taken as necessary.
- One day before treatment with SDF, please brush your child's teeth with the provided toothpaste, and continue to use this toothpaste for 2 days after the tooth treatment.
- You will need to collect pee sample for a total of three times. Three units of pee containers and ice-boxes will be provided. Each of the pee samples collection is a 24 hour collection
- Before the SDF treatment, the first pee sample should be collected.
- The SDF treatment procedure: dry the affected teeth, place a small amount of SDF on the affected teeth, allow SDF to dry for one minute and then rinse.
- Immediately after the SDF treatment, the second pee sample should be collected.
- One day after the SDF treatment, the third pee sample should be collected.
- Your child's teeth will be examined at the first month after the treatment.
- For the hair sample, it will be collected before the SDF treatment, followed by day 7, day 14, day 30, day 60, day 75 and day 90.
- Please keep the hair at the back of the head for three months. The hair length should be at least 5cm from the scalp. If hair cut is required, please do not cut the hair in this area. Hair sample collection will be performed by the researcher.
- The researcher will pay a home visit to collect the pee and hair samples.
- All of the dental fillings and extractions will be provided by our researcher as necessary.

8. What will be the benefits of the study:

(a) To participant?

Contribution towards the science in development of understanding of body's reaction after SDF treatment. The SDF treatment for this study is free of charge. Sealants, fillings and fluoride application are free of charge. For extractions, fillings involving crown, denture, braces or treatment under sedation or general anesthesia, the fee will be charged as usual.

A free toothbrush and toothpaste will be given as a token of appreciation.

(b) To the investigator?

Investigator would understand how the body react towards SDF. This will improve the patient's dental care and welfare.

9. What are the possible drawbacks?/ risks / complications / adverse effects that may happen?

The main side effects of SDF is staining of the affected tooth. The colour of decayed tooth will turn to dark brown or black. Hence, the application of SDF to the front teeth depends on patient and/or parents' preference. A discussion will be made to decide on the tooth to receive the SDF treatment.



before and after SDF Application on front teeth
(Rosenblatt et al J Dent Res 88(2): 116-125, 2009)

Direct contact of SDF on the gum could cause ulcer, which is temporary. Cotton or gauze will be placed to protect the gums during the treatment.

Upon application, a child may notice a metallic taste, and this will go away rapidly.

10. Who should not enter the study?

1. Children aged below 4 years and above 10 years
2. Children who do not have decayed teeth
3. No consent and permission to join the study
4. Taking medications/over the counter medications/supplements
5. Children with medical problems
6. Known allergy to silver or fluoride
7. Presence of ulcer in the mouth which has not heal completely
8. Children whose teeth have been filled with silver fillings or stainless steel crown
9. Children whose teeth have been filled with a material that contain glass particles known as glass ionomer, within a year before this research

11. Can I refuse to take part in the study?

Your participation is totally voluntary. You can withdraw yourself from the study at anytime you wish. You do not need to explain why you prefer not to take part in the study. This will not affect or compromise your dental treatment.

12. Who should I call if I have questions?

If you have any questions about the study or if you think you have a study related injury and you want information about this study, please contact the study doctor, Dr Lim Siau Peng at telephone number 014-9138366.

If you have any questions about your rights as a participant in this study, please contact: The Secretary, Medical Ethics Committee, Faculty Of Dentistry at telephone number: 03-79676460.