Consent form, Version 3, 12 December 2022

Influence of silver diamine fluoride application on the restorative treatment for root caries

Dear participant:

We sincerely invite you to take part in the above captioned research project conducted by the Faculty of Dentistry, the University of Hong Kong. Please read through the following information of this study, and please contact us without hesitation if you have any question or need more information. If you are willing to participate, please sign the attached consent form.

The aim of the proposed study is to investigate the influence of prior silver diamine fluoride (SDF) application on the restorative treatment for root caries. If you choose to participate, we will treat your decayed root, if appropriate, by placement of restoration using dental hand instruments and glass-ionomer material. You will be randomly selected to receive a topical application of SDF solution (an agent for prevention of tooth decay and has been shown to be safe) or not, around 10 weeks before we provide fillings. These are established dental treatment procedures, thus, there will be no special risk and no known adverse effect for you. The experimental element of the treatment is the prior SDF application before filling up the decayed root.

We will conduct follow-up examinations at 6, 12, 18 and 24 months after the treatment to evaluate the outcomes. In addition, we would like to find out your satisfaction with the treatment and your opinion about aesthetics and your oral health conditions through a questionnaire survey. All the dental examination and treatment will be free of charge. Upon completion of the dental treatment and follow-ups, you will receive oral care products as souvenirs.

Participation in this study is completely voluntary and free of charge. You can choose not to participate or to withdraw at any time without any adverse consequences.

All personal information collected in this study will be kept confidential and only be used for research purposes. All collected information will be kept for 10 years and will be safely disposed after the aforesaid storage period.

The study is reviewed by the Institutional Review Board (IRB) of The University of Hong Kong / Hospital Authority Hong Kong West Cluster. If you have any questions regarding participant's rights, you can contact IRB Secretary by 2255 3923. You are welcome to contact us at 2859 0291 during office hours if further information is needed regarding the study details.

Clinical Assistant Professor
Chloe Meng Jiang
12 December 2022

ID: Name:

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PARTICIPANT CONSENT FORM

☐ I confirm that I have read and understand the information sheet for the above study and have had the opportunity to ask questions.

☐ I understand that the participation is voluntary and I are free to withdraw at any time without giving any reason, and without my medical care or legal rights being affected.

☐ I understand that sections of any of my medical notes may be looked at by responsible individuals from Faculty of Dentistry, the University of Hong Kong or form regulatory authorities where it is relevant to my taking part in research. I give permission for these individuals to have access to my records.

☐ I agree to take part in the above study.

Confidentiality

You have the rights of access to personal data and publicly available study results, if and when needed.
Under the laws of Hong Kong (in particular the Personal Data (Privacy) Ordinance, Cap 486), you enjoy or may enjoy rights for the protection of the confidentiality of your personal data, such as those regarding the collection, custody, retention, management, control, use (including analysis or comparison), transfer in or out of Hong Kong, non-disclosure, erasure and/or in any way dealing with or disposing of any of your personal data in or for this study. For any query, you should consult the Privacy Commissioner for Privacy Data or his office (Tel No. 2827 2827) as to the proper monitoring or supervision of your personal data protection so that your full awareness and understanding of the significance of compliance with the law governing privacy data is assured.
By consenting to participate in this study, you expressly authorize:

- the principal investigator and the research team and the ethics committee (Institutional Review Board of the University of Hong Kong / Hospital Authority Hong Kong West Cluster) responsible for overseeing this study to get access, to use, and to retain your personal data for the purposes and in the manner described in this informed consent process; and
- the relevant government agencies (e.g. the Hong Kong Department of Health) to get access to your personal data for the purposes of checking and verifying the integrity of study data and assessing compliance with the study protocol and relevant requirements.

Name of participant	Date	Signature
Name of research assistant	Date	Signature