

Version 2.0 Dated 15th March 2020

PARTICIPANT INFORMATION SHEET AND INFORMED CONSENT FORM
(for parents/ guardians)

1. Study Title: "The Use of Silver Diamine Fluoride and Papain-Based Gel for Management of MIH Affected Molar in Paediatric Patients: A Randomised Controlled Trial"

2. Name of investigator and institution:
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3. Name of sponsor : Faculty Research Grant, Faculty of Dentistry, University Of Malaya

PARTICIPANT INFORMATION SHEET

Please read the following information carefully. Do not hesitate to discuss any questions you may have with your doctor.

Study Title: “The Use of Silver Diamine Fluoride and Papain-Based Gel for Management of MIH Affected Molar in Paediatric Patients: A Randomised Controlled Trial”

Introduction

Molar Incisor Hypomineralisation (MIH) is a disease, which causes the discoloration of the enamel, either being whiter than normal or having shades of cream, yellow or brown. This discolouration is usually restricted to a small spot or bigger patch, but the whole tooth surface may be affected in severe cases. Sometimes the enamel appears dull, opaque and also crumbles easily compared to the normal enamel translucency and the shiny hard surface. Other times the surface enamel is shiny but irregular, with pits or grooves being visible from some angles. The tooth is weak which lead to rapid breakdown, fast caries progression and very sensitive. It usually requires complex and multiple treatment visits and if it is severely damaged, extraction maybe required.

This study attempts to investigate the treatment effect of silver diamine fluoride (SDF) and deproteinizing agent on hypomineralized molar teeth. Early treatment intervention enables us to provide comfortable dental experience especially in young children. Therefore, your child is cordially invited to participate in our study.

What is the purpose of this study?

This study aims to compare the clinical outcome on hypomineralized molar teeth when treated with silver diamine fluoride (SDF) and papain-based gel as deproteinizing agent.

What are the procedures to be followed?

We seek your permission to do dental check-up and taking intraoral radiograph and photograph. Your child will be randomly assigned to one of three treatment groups. The details of treatment for each group are as in the table below:

| Groups | Treatment |
|--------|---|
| 1 | Tooth restored with High Viscosity Glass Ionomer Cement (HVGIC) |
| 2 | Tooth surface treated with SDF and restored with HVGIC |
| 3 | Tooth surface treated with SDF and papain-based gel and restored with HVGIC |

Following treatment, your child is required to come for follow up after 6 and 12 months. All the information collected and generated will be kept strictly confidential and all information will be anonymous so that you cannot be identified from it.

Who should not enter the study?

Every individual with the disease can volunteer to participate in the study. However, your child may be exempted from participating in the study if they had problem as listed below:

1. Medical problem with difficulty to perform oral hygiene independently
2. Medical problem with difficulty to comprehend instruction
3. Affected teeth with extensive damage to crown structure require extraction
4. Affected teeth with deep extensive damage to crown structure require root canal treatment
5. Affected teeth with a good restoration that do not require redo
6. Child with silver allergy

What will be the benefits of the study?

(a) To participant?

You will receive a comprehensive dental treatment in the form of restoration and preventive care in the Paediatric Dental Clinic, Faculty of Dentistry, University of Malaya. You will not be charge for any types of treatment done on that affected tooth.

(b) To the investigator?

We will be able to use the information gathered from the research to improve treatment and management of patients with similar problem.

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

The immediate complication may arise from silver diamine fluoride application is black staining on treated tooth. However, the affected tooth is often discoloured due to the nature of the lesion and or caries. Alternatively, this discoloration can be mask by crowning.



Moreover, your child may experience allergic reaction towards the dental materials that are going to be used, but it is rare. Symptom of allergy includes rashes, difficulty breathing, dizziness, swelling around the mouth, throat or eyes, fast pulse, and excessive sweating. Please inform the researcher and get medical attention immediately if your child has the symptom.

Can I refuse to take part in the study?

Your participation is totally voluntary. You do not have to explain why you prefer not to take part in the study.

Who shall I contact if I have additional questions during the study?

The best person to consult will be your doctor who will be working with us closely. Should you need to find out more about the details of the study, you are welcome to contact us at any time.

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CONSENT BY PARTICIPANT'S PARENT/GUARDIAN FOR RESEARCH
FACULTY OF DENTISTRY, UM, K.L.

I, Identity Card No. of
**(Name of participant's parent/guardian)*
.....hereby agree
.....
(Address)
to allow my daughter/son named to take part in the
(Name of participant)
research specified below:

Title of Study: "The Use of Silver Diamine Fluoride and Papain-Based Gel for Management of MIH Affected Molar in Paediatric Patients: A Randomised Controlled Trial"

After knowing and understanding all the possible advantages and disadvantages of this research, I voluntarily consent of my own child to participate.

I understand that my child can withdraw from this research at any time.

Signature Date
**(Participant's parent/ guardian)*

IN THE PRESENCE OF

Name,

I/C No., Position

Signature Date
**(Witness for signature of participant's parent/ guardian)*

I confirm that I have explained to the *participant's parent/guardian the nature and purpose of the above mentioned research.

Signature Date
(Attending doctor)

* Delete where not applicable