2025

Clinical Trial Consent

NCT : NOT YET AVAILABLE DATE: 29/6/2025

Informed Consent Form

National Research Centre Medical Research Ethics Committee

English Study Title: Clinical evaluation of resin based versus giomer fissure sealants on MIH affected permanent molars (RCT)

Principal Investigator: Rabab M. Abd Elhakam
Sponsoring Entity: Self-funded
Supervising Physician: Rabab M. Abd Elhakam / Department of Orthodontics and Pediatric Dentistry
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Introduction

Your son or daughter is invited to participate in a comparative study of two fissure sealants (resin based and giomer based) available on the market to support your child MIH first permanent molar (a randomized controlled trial). They have been invited because they suffer from molar incisor hypominerlisation. This document provides information about the study. Before deciding to participate, it is important to understand the purpose of the research and what it involves. You may take this form with you to discuss it with others before making your decision. If you have any questions, please ask the study physician or their representative. If you decide to participate, you will be asked to sign this form and will receive a copy.

MIH (Molar Incisor Hypomineralization) is becoming a global public health concern, affecting about 13–14% of people. More children are being diagnosed with it, making it a common issue for dentists who treat kids. prevalence of MIH in Egypt was recorded about 2.7%.

Treatment with fissure sealant is one of the followed protocols to support and augment affected molar and prevent molar fast decay. making it an excellent option for treating young children who suffer from MIH.

This study has been reviewed by the Independent Review Board at the National Research Centre and will be conducted according to the ethical principles of the Declaration of Helsinki and Good Clinical Practice (GCP) guidelines.

Participation is voluntary. You are free to choose not to participate or to withdraw at any time. Your choice will not affect the medical care you normally receive outside the scope of this study.

Purpose of the Study

this study aims to evaluate the clinical success of giomer and conventional resin-based sealants applied on first permanent molars (FPMs) affected by MIH.

Study Design

This is a **Single-blinded randomized clinical trial**.

- **Randomized:** The treatment received will be chosen randomly using an automated system (similar to a lottery), with an equal chance of receiving either product.
- **Single-blinded:** You will not know which specific brand is being used; only the physician and the sponsoring entity will have this information to minimize psychological bias.

Procedures

If you agree to participate, the supervising physician will conduct medical examinations to ensure eligibility. Participants will be randomly assigned to one of two groups:

- Group 1: Resin based sealant (Fisseal, Promedica , Germany).
- Group 2: Giomer based sealant (BeautiSealant, Shofu, Japan).

The material will be applied without the use of needles or anesthesia and is painless. Clinical examinations and sometimes medical imaging will be required every 6 months. You will be asked about your health and any issues encountered. A final visit will occur after 12 months.

Visit Schedule:

1. **Initial Screening (Day 1):** Signing the informed consent, collecting demographic data (name, date of birth, gender), medical history, and a comprehensive dental examination.
2. **Treatment Visit:** Application of either Fisseal or Beautisealant.
3. **Follow-up Visits (6 and 12 months):** Clinical dental examination.

Potential Benefits and Risks

The two method may effectively enhance protection from decay and reduce sensitivity. Giomer sealants release fluoride but wear down faster and may need more frequent replacement. The chalky, porous enamel in MIH teeth doesn't hold sealant as well as healthy enamel, so sealants may need re application.

Confidentiality and Withdrawal

All research information will remain confidential to the extent permitted by law. Data will be used for research purposes only and may be published in scientific journals without revealing the identity of participants. You have the right to withdraw from the study at any time without penalty.

Contact Information

For any questions or if you experience any research-related injury, contact the supervising physician:

- **Physician:** Rabab M. Abd Elhakam
- **Phone:** +201069493113
- **Email:** rm.abdel-hakam@nrc.sci.eg , dr.rabab_nrc@hotmail.com

For questions regarding your rights as a research participant, you may contact the Medical Research Ethics Committee at the National Research Centre.

Participant/Guardian Attestation

I have read (or have been read) the information regarding this study. I have had the opportunity to ask questions and have received satisfactory answers. I voluntarily agree to participate in this study.

- **Participant/Guardian Name:** _____
- **Signature/Thumbprint:** _____
- **Date:** _____
- **Witness Name (if applicable):** _____
- **Witness Signature:** _____

Investigator's Statement: I have explained the nature and purpose of the study to the participant/guardian and have answered all their questions.

- **Investigator Name:** Iman Ahmed Mohamed Karim
- **Signature:** _____
- **Date:** _____