Participant Information Sheet

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Study Title: A combined high-power light-curing and preheating protocol for class I posterior composite restorations: A 12-month randomized controlled clinical trial

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Introduction

You are being invited to take part in a research study. Before you decide whether to participate, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Ask us if there is anything that is not clear or if you would like more information.

What is the purpose of the study?

This study aims to compare four different methods of placing dental fillings (composite restorations) in back teeth. The methods involve:

1. Standard filling technique (conventional method)
2. High-power light curing (faster curing)
3. Preheating the filling material before placement
4. Both preheating and high-power light curing

We want to find out which method provides the best results in terms of filling quality, durability, and patient comfort.

Why have I been invited?

You have been invited because you are between 18 and 50 years old and require fillings in four of your back teeth (molars). These teeth have cavities that need to be restored with composite (tooth-colored) filling material.

Do I have to take part?

No. Participation is entirely voluntary. If you decide not to take part, it will not affect the standard of care you receive. If you decide to take part, you are still free to withdraw at any time and without giving a reason.

What will happen if I take part?

If you agree to participate:

1. **Initial Examination:** Your teeth will be examined, and X-rays may be taken to confirm the need for fillings.
2. **Filling Placement:** Four of your back teeth will receive fillings using one of the four methods mentioned above. The method used for each tooth will be chosen randomly.
3. **Follow-up Visits:** You will be asked to return for check-ups at:
    - 30 minutes after the procedure
    - 24 hours after the procedure
    - 6 months after the procedure
    - 12 months after the procedure

At each visit, the fillings will be examined and assessed for quality, fit, and any sensitivity.

What are the benefits of taking part?

- You will receive high-quality dental fillings at no cost
- You will help advance dental science and improve future treatments
- Your fillings will be monitored carefully over 12 months

What are the possible risks?

The risks are similar to those of routine dental fillings:

- Mild post-operative sensitivity (which usually resolves within a few days)
- Slight discomfort during the procedure (local anesthesia will be used)
- Very low risk of allergic reaction to materials (inform us if you have known allergies)

The study uses materials that are already approved and widely used in dentistry.

Will my information be kept confidential?

Yes. All information collected during the study will be kept strictly confidential. Your personal details will not be disclosed in any reports or publications. You will be assigned a unique code number, and your name will not appear in any study records

What happens if I withdraw from the study?

If you decide to withdraw at any time, your dental treatment will continue as usual. Any data collected up to that point may still be used for the study analysis unless you request otherwise.

Who has approved this study?

This studyhas been reviewed and approved by the Institutional Review Committee of the College of Medicine, University of Diyala (Approval No. 2025RJK965; dated 22 October 2025). This ensures that the study meets ethical and scientific standards.

What should I do if I have questions?

If you have any questions or concerns about the study, please contact:

Dr. Rabeia J. Khalil
College of Dentistry, University of Diyala

07705888527

If you have concerns about your rights as a research participant, please contact the Institutional Review Committee:

College of Medicine, University of Diyala
Phone: 07721863978
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Declaration

I have read and understood the information provided. I have had the opportunity to ask questions, and I understand that my participation is voluntary. I agree to take part in the study.