

INFORMED CONSENT FORM

Clinical Trial Document

****Official Title of the Study:****

Evaluation of the Effect of a Hydroxyapatite-Forming Desensitizing Agent on Postoperative Sensitivity in Composite Restorations

****NCT Number:**** NCT04540835

****Sponsor:**** Baskent University

****Document Date:**** 02 November 2019 (Version 1.0)

1. Title of the Study

Evaluation of the Effect of a Hydroxyapatite-Forming Desensitizing Agent on Postoperative Sensitivity in Composite Restorations.

2. Number of Participants

The planned number of volunteers for this study is 50.

3. Duration of Participation

The expected duration of your participation is 6 weeks.

4. Purpose of the Study

This study aims to evaluate the effect of Toothmate Desensitizer in reducing or preventing tooth sensitivity after fillings. You are invited because you have deep cavities. After treatment, sensitivity may occur for several weeks. Toothmate Desensitizer may reduce or prevent this sensitivity. The product is approved and licensed, widely used worldwide, and does not cause pain when applied.

5. Eligibility Criteria

You must be 18–65 years old, need a composite filling, be likely to feel sensitivity, and be able to attend follow-ups.

6. Study Procedures

You will be examined by the research dentists. Two teeth will be included. You will complete a Sensitivity Diary for 1 week, attend follow-ups at 1 week and 6 weeks, and sensitivity will be tested.

7. Participant Responsibilities

Follow the study plan and report any problems.

8. Possible Benefits

Your tooth may have less sensitivity, and the study will provide important knowledge for dental science.

9. Possible Risks

All materials used are safe and well known in dentistry. No harmful effects are expected.

10. Compensation in Case of Harm

If you are harmed due to the study, costs will be covered by Baskent University.

11. Contact in Case of Problems

Baskent University, Faculty of Dentistry, Yukari Bahcelievler, 82. Sk. No:26, Çankaya/Ankara. Tel: (0312) 203 00 00. Mobile: 0537 898 6689.

12. Costs and Payments

You will not be asked to pay for participating. The cost of fillings will also not be charged to you.

13. Sponsor of the Study

The study is sponsored by Baskent University.

14. Payments to Participants

No payments will be given. Only necessary study expenses will be covered.

15. Confidentiality of Information

Your data will be coded and kept confidential. Results will be published only for scientific purposes without your identity.

16. Withdrawal from the Study

The dentist may remove you if needed, but your treatment will continue. Your data may still be used scientifically.

17. Other Treatments

No additional treatments outside the study.

18. Voluntary Participation and Right to Withdraw

Taking part is voluntary. You can leave anytime without affecting your treatment.

19. Sharing of New Information

If new information appears, it will be shared with you so you can decide whether to continue.

Participant's Statement

I have been informed about this clinical study at Baskent University. I understand that my medical information will remain confidential, and results will only be used for scientific purposes. I can leave the study at any time without affecting my treatment. I freely agree to participate.

Signatures:

Participant: _____ Date: _____

Parent/Guardian (if applicable): _____ Date: _____

Investigator: _____ Date: _____

Witness: _____ Date: _____