

College of Dentistry – University of Baghdad**Patient Information Sheet**

You are invited to participate in a scientific research. Please take your time to read the following information carefully before you decide whether or not you wish to participate. You can ask for clarifications or any more information about the study from the researcher and you can discuss this with outsiders.

Information about the research (to be written by the researcher in a simple language answering the following questions when applicable)**1. Study title**

Effectiveness of a Hydroxyapatite-Containing Toothpaste Versus Mouthwash in Preventing White-Spot Lesions During Fixed-Appliance Orthodontic Treatment:
Randomized Clinical Trial

2. What is the purpose of this study?

To evaluate and compare the effectiveness of a hydroxyapatite-containing toothpaste versus a hydroxyapatite-containing mouthwash in preventing or decreasing the incidence of WSLs during fixed-appliance orthodontic treatment.

3. Where will the study be conducted?

The study will be conducted as a multicenter study in different dental clinics.

4. What are the procedures to be followed and what will you be asked to do at each visit?

You will be asked to brush your teeth three times and to use the mouthwash twice a day. You will also be required to attend regular visits to monitor the health of your teeth and gums, as well as to undergo dental examinations and photographs. In addition, saliva samples will be collected to evaluate the effect of the materials on the teeth. All steps will be explained to you in detail, and you will be instructed on the correct use of the toothpaste and mouthwash.

5. How long will the participation in the study last?

6 months

6. If you decided to taking part in the study, will the treatment be different from the treatment you would get otherwise?

There is no difference in the treatment plan that usually decided for your condition.

7. Who should not enter the study?

1. History of previous orthodontic treatment.
2. Bleaching or topical fluoridation within the last six months.
3. Severely rotated any of the study teeth (limiting the appearance of facial surfaces).
4. Visible signs of caries, fluorosis, hypocalcification, or other developmental defects.
5. Restoration on the labial surface of the study teeth.
6. Systemic or endocrine conditions (e.g., cardiac pacemakers, diabetes mellitus).
7. Craniofacial anomalies and clefts.

8. What will be the benefits of the study?

- a) To the participant? Reduce or eliminate WSLs around orthodontic bracket
- b) To the investigator? finish orthodontics master research requirement

9. What are the possible risks of taking part? No risks

10. If you feel severe discomfort or pain during the study, would you be able to take any relief medication? yes, you can

11. Will your participation in the study interfere with your daily activities?

No, it will not.

12. Will you be informed of the results of the study?

If you like, it will be submitted to you

If you agree to participate in this study, we will ensure your confidentiality with no one except the study researchers have the right to access your dental (medical) notes.

Participation in this study is entirely voluntary and you are free to refuse to take part or to withdraw from the study at any time without having to give a reason and without this affecting your future medical care or your relationship with medical staff looking after you.

Thank you for reading this Information Sheet and considering your participation in this study

Consent Form

	Please tick to confirm
I confirm that I have read and understood the information sheet for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	
I understand that my participation is voluntary and that I am free to withdraw at any time without any medical/dental care affected.	
I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from the College of Dentistry – University of Baghdad where it is relevant to my taking part in this research. I give permission to these individuals to have access to my records.	
I agree to take part in the above study.	

Regarding any information and records taken during the research please specify your acceptance to share them as you desire:

	Personal data	X-rays	Extra-oral photographs	Intra-oral photographs	Others
Confidential					
For consultation					
For teaching					
For conferences					
For publication					

	Name	Signature	Date
Participant			
Parent/guardian (if appropriate)			
Person taking consent			

Person to contact:

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