Kingdom of Saudi Arabia
Ministry of Education
Umm Al -Qura University
Faculty of Dentistry

Cover Page

Official Title of the Study	Short-term Effects of Acacia Arabica Mouth Rinse and paste on Plaque-induced Gingivitis
NCT Number	Not yet assigned
Unique Protocol ID	HAPO-02-K-012-2024-10-2310
Document Type	Study -Informed Consent
Document Date	1-January-2025

Informed Consent Form for Participation in A Clinical Study

Protocol Title: Anti-microbial effect of Acacia Arabica Extract on Gingival and periodontal Health of Dental Patients

Aim/s of the study:

- To investigate the antimicrobial effect of Acacia Arabica on gingival and periodontal health
- To study the effect of Acacia Arabica on epithelial wound healing by in vitro study

Participation is voluntary/optional:
You are completely free to choose whether to join the study or not. If you choose not to participate in the study, your management plan will proceed according to the standard guidelines and will not be adversely affected with your decision.

Study Procedures:
If you decide to participate in this study, you will go through the following procedures

- Examination and treatment: treatment plan and follow up care of your condition will be offered during the visits.
- During visit, saliva sample will be taken.
- During the visit, scaling and oral hygiene instruction along with education of how to use oral hygiene tool.
- Measurements of periodontal pockets, bleeding on probing and gingival crevicular fluid will also be taken during visits.
- Also, Acacia Arabica extract will be either in mouth wash, paste or gel and will be provided for regular use according to study instruction.
- Follow up visits will be continued as regular to ensure complete treatments of lesion or referral to hospital if needed.

Which part of the study is experimental:
The purpose of this form is to get your permission to participate in a study assessing Effect of Acacia Arabica Extract on Gingival and periodontal Health of Patients. You will be offered a regular follow up visit/s at Paediatric Dentistry clinics of Umm Al-Qura University Teaching Hospital (UQUDent).

Expected benefits:
The benefits of your visits and participation in our study is to diagnose your gingival condition and provide immediate treatment depending on your condition. Also, your participation will allow to explore the effect of Acacia Arabica extract on gingiva and reach to a mechanism to answer How Acacia Arabica extract will help and assess epithelial wound healing.

Expected risks:
Periodontal measurements are usually uncomfortable but professional trained examiner will carry this procedure.

Alternatives to participation:
If you choose not to participate, your management and follow up care will proceed according to the treatment plan of your dentist at UQU Dental Hospital.

Freedom of withdrawal: You have the right of withdrawal from the study at any time if you have unacceptable adverse events, cannot cope with assessment, or follow up procedures or due to any other issue without explaining the cause of withdrawal, and you will not be subjected to any change in your treatment plan.	
Study revision and approval: This study was revised and approved by the Institutional Review Board-IRB (research ethics committee at Umm Al-Qura University).	
How information and results will be used: The result of this study will be published in a scientific journal to enable all dentists of potential useful use of Acacia Arabica extract for their patients.	
Confidentiality: Your name or any identifying information will not be used in any study document except your hospital file number. All your data will be concealed from all study participants except the treating dentist.	
How new information will be communicated? Any new data regarding the study will be presented to you by the research team. **In case you have an inquiry about the study, you can contact a member from the research team:** Name: Dr. Elham Nafea Alsahafi Email: ensahafi@uqu.edu.sa Name: Dr Mustafa Tashkandi Email: mmtashkandi@uqu.edu.sa	

Consent statement

I hereby confirm that all aspects related to the study have been explained to me including aims and procedures and that the study does not include any experimental therapies and that my participation is voluntary with no extra-expenses and there is no payment offered to me for participation.

Signature of the participant:

Date of consent *(To be personally dated by the participant)*