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
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Clinical Trial Protocol

1. Study Title

A Randomized Controlled Trial to Evaluate the Effectiveness of Acacia arabica Tooth Gel and Mouth Rinse on Gingival and Periodontal Health

2. Study Objectives

- **Primary Objective:** To assess the efficacy of commercially available Acacia arabica tooth gel (Gum Tone) and Lab made mouth rinse in improving gingival and periodontal health compared to a control (The main measure is CAL loss and gain).
- **Secondary Objective:** To evaluate the effect of acacia arabica on wound healing, antimicrobial and, antioxidant property in (in vitro model) using isolated human gingival fibroblast.

3. Study Design

- **Type:** Randomized, three-arm, parallel-group, single/double-blinded controlled trial.
- **Arms:**
    - **Control Group:** Regular toothpaste and plain water for rinsing.
    - **Intervention Group 1:** Tooth gel containing Acacia arabica (Gum Tone gel).
    - **Intervention Group 2:** Mouth rinse containing Acacia arabica.

4. Participants

Inclusion Criteria:

- Adults aged 18–65 years.
- Presence of mild to moderate gingivitis or periodontal disease.
- No systemic disease affecting oral health (e.g., diabetes, immunocompromised conditions).
- No history of allergy to the study products.
- Willingness to comply with the study protocol.

Exclusion Criteria:

- Use of antibiotics or anti-inflammatory drugs within the last 3 months.
- Pregnant or breastfeeding women.
- Smokers or tobacco chewers.
- Current orthodontic treatment or advanced periodontitis.

5. Sample Size

- **Estimated Sample Size:** Based on the desired statistical power (e.g., 80%) and significance level (e.g., 0.05). For three groups, approximately 30–50 participants per arm.

6. Randomization

- **Method:** Use computer-generated random allocation to assign participants to one of the three arms.
- **Allocation Concealment:** Use sealed, opaque envelopes or electronic randomization software.

7. Intervention Protocol

- **Control Group:**
  - Brush with standard toothpaste twice daily.
  - Rinse with plain water after brushing.
- **Acacia arabica Tooth Gel (Gum tone) Group:**
  - Brush with standard toothpaste twice daily
  - Apply after brushing Acacia arabica tooth gel twice daily for 2 minutes.
  - Rinse with plain water after brushing.
- **Acacia arabica Mouth Rinse Group:**
  - Brush standard toothpaste) twice daily.
  - Use 10–15 mL of Acacia arabica mouth rinse for 1 minute after brushing.
- **Duration:** 4 weeks.

8. Outcome Measures

Primary Outcomes:

1. **Plaque Index (PI):** Assessed at baseline, 2 weeks, and 4 weeks.
2. **Gingival Index (GI):** Assessed at baseline, 2 weeks, and 4 weeks.
3. **Bleeding on Probing (BOP):** Measured at baseline, 2 weeks and 4 weeks.
4. **Collect saliva (spitting 5 min) and GCF:** at baseline, 2 weeks and 4 weeks.

Secondary Outcomes:

1. Proliferation rate (use 5, 10, 15ug) of Acacia in culture media of hGFs and use MTT assay for 5 days.
2. Wound healing (use same conc. In the above).
3. Collect culture media of wound healing assay for future (ROS, ELISA or WB).

9. Blinding

- **Blinded Outcome Assessment:** The clinical examiner should be blinded to group allocation.
- **Blinded Participants (if possible):** Use identical packaging for tooth gel and placebo to maintain blinding.

10. Ethical Considerations

- Obtain approval from UQU IRB Board.
- Register the trial in a clinical trial registry
- Provide informed consent to all participants.

11. Data Collection

- **Baseline Data:** Demographics, oral hygiene habits, periodontal indices.
- **Follow-up Data:** Clinical outcomes at 2 weeks, 4 weeks,

12. Statistical Analysis

- **Descriptive Statistics:** Calculate means and standard deviations for continuous variables (e.g., PI, GI).
- **Inferential Statistics:**
    - Use ANOVA or Kruskal-Wallis test to compare outcomes across the three groups.
    - Perform post-hoc analysis for pairwise comparisons if significant differences are found.
    - Use paired t-tests or Wilcoxon tests for within-group comparisons over time.
- **Software:** Use SPSS, R, or similar software for analysis.