STUDY PROTOCOL

Official Title: *Effect of Menstrual Cycle on Postoperative Sensitivity and Rebound Pain in Posterior Composite Restorations: A Double-Blind Split-Mouth Clinical Study*

Unique Protocol ID: FIRAT-DENTISTRY ADEMGOK-001

NCT ID: .....

Date: *01.09.2022*

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Study Objectives:

- **Primary Objective:** To evaluate the effect of menstrual cycle phases on postoperative sensitivity (POS) following direct posterior composite restorations.
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- **Secondary Objective:** To assess whether menstrual cycle phases influence the incidence or severity of rebound pain (RP) after inferior alveolar nerve block (IANB).

Study Design:

- **Type:** Double-blind, split-mouth, randomized clinical trial
- **Study Groups:**
    - **Menstrual Phase Group (MPG):** Restorations performed during **days 1-3** of menstruation.
    - **Ovulatory Phase Group (OPG):** Restorations performed on **days 11-16**, depending on cycle length.
- **Number of Participants:** 35 women, each receiving two restorations
- **Total:** 70 restorations).
- **Masking(Blinding):**
    - The operator performing the restorations and the researcher assessing the outcomes were blinded to menstrual cycle phases.

Eligibility Criteria:

Inclusion Criteria:

- Women aged 18-45 years
- Regular menstrual cycles (26-32 days)
- No hormonal contraceptive use
- Vital posterior mandibular molar teeth requiring restorative treatment
- Good oral and periodontal health

Exclusion Criteria:

- Irregular menstrual cycles or hormonal disorders
- Pregnancy or lactation
- Use of analgesics or anti-inflammatory drugs within 48 hours before treatment
- Severe periodontal disease or need for endodontic treatment

Interventions & Procedures:

- **Anesthesia:** Inferior alveolar nerve block (**IANB**) with articaine hydrochloride with epinephrine (1:100,000)
- **Restorative Material:** Clearfil Universal Bond Quick (Kuraray, Japan) and Clearfil Majesty Posterior (Kuraray, Japan) .
- **Postoperative Sensitivity (POS) Assessment:**
    - VAS (0-10) measured at Day 1, Day 2, and Day 3 after restoration.
- **Rebound Pain (RP) Assessment:**
    - VAS (0-10) measured at Hour 4, Hour 8, and Hour 12 after anesthesia resolution.

Statistical Analysis:

- **Cochran's Q test** for intragroup comparisons
- **McNemar's test** for post-hoc analysis
- **Chi-Square test or Fisher's Exact Test** for intergroup comparisons
- **Bonferroni correction** for multiple comparisons
- **Significance Level:** $p < 0.05$

Ethical Approval:

- Non-Interventional Research Ethics Committee of Firat University
- Reference No: 2022/08-07
- **ClinicalTrials.gov Registration No:** has not been created yet

Date of creation: 01.09.2022