STUDY PROTOCOL

Title: Evaluation of the Effects of Dexamethasone-Enriched Platelet-Rich Fibrin on Postoperative Pain, Edema, and Trismus Following Impacted Mandibular Third Molar Surgery: A Randomized Split-Mouth Clinical Trial

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1. Background and Rationale

Impacted mandibular third molar surgery often results in postoperative pain, swelling, and trismus, negatively affecting patient recovery. Platelet-rich fibrin (PRF) has been used to improve healing and reduce complications. This study investigates the enhanced effects of PRF prepared from blood enriched with dexamethasone, a corticosteroid with anti-inflammatory properties.

2. Objectives

- **Primary Objective:** To assess the effect of dexamethasone-enriched PRF on postoperative pain after mandibular third molar extraction.
- **Secondary Objectives:** To evaluate effects on postoperative edema, trismus, and analgesic consumption.

3. Study Design

A randomized, controlled, double-blind, split-mouth clinical trial. Each patient will receive both interventions in contralateral extraction sites: standard PRF vs dexamethasone-enriched PRF.

4. Participants

Inclusion Criteria:

- Healthy adults aged 18–25 years
- Bilateral symmetrical impacted mandibular third molars requiring extraction
- No systemic disease
- Good oral hygiene
- Provided written informed consent

Exclusion Criteria:

- Systemic or immunological disorders
- Recent corticosteroid or anti-inflammatory use
- Pregnancy or lactation
- Allergies to study medication
- Poor oral hygiene or active oral infections
- Temporomandibular joint disorders affecting mouth opening

5. Interventions

- Control: PRF prepared from standard venous blood.
- Test: PRF prepared from venous blood mixed with 4 mg dexamethasone sodium phosphate prior to centrifugation.

6. Outcome Measures

- **Primary Outcome:** Postoperative pain measured by Visual Analog Scale (VAS) at 24, 48, and 72 hours.
- **Secondary Outcomes:** Edema, trismus, and analgesic consumption measured on postoperative days 1, 3, and 7.

7. Sample Size

Sixteen patients (32 extraction sites) based on power calculation.

8. Statistical Analysis

SPSS 22.0; Independent samples t-test or Mann–Whitney U test depending on data distribution. Significance threshold $p < 0.05$.

9. Ethics

Approved by Sivas Cumhuriyet University Ethics Committee (Approval No: 2023-07/02, Date: 18.07.2023). Written informed consent obtained.

10. Data Confidentiality

Anonymized data storage, access limited to study personnel, data retained for 5 years.