Research Protocol: WHO-Compliant Format

1. Title of the Study

Comparison of Different Techniques for Preserving the Alveolar Ridge After Tooth Extraction: A Clinical, Radiological, and Histological Study.

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2. Background and Rationale

Tooth extraction often leads to significant dimensional changes in the alveolar ridge, particularly horizontal and vertical bone resorption. These changes can compromise esthetic outcomes and complicate future implant placement. Although biological remodeling is inevitable, various interventions such as grafting with synthetic biomaterials have shown promise in minimizing bone loss. Calcium phosphate and calcium sulfate are among the most studied synthetic grafts due to their biocompatibility and osteoconductive properties.

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3. Research Problem

Alveolar ridge resorption post-extraction presents a major clinical challenge, affecting both function and esthetics. There is a pressing need to identify effective techniques that preserve ridge dimensions and enhance tissue healing to facilitate optimal implant placement.

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4. Objectives

- To evaluate the effectiveness of a synthetic bone graft (calcium sulfate/tricalcium phosphate) in preserving the alveolar ridge.
- To compare clinical, radiographic, and histological outcomes between two preservation techniques.
- To assess post-operative pain, soft tissue healing, and bone density six months after extraction.

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5. Research Questions

- Does the use of calcium sulfate/tricalcium phosphate reduce bone resorption compared to Sticky Bone technique?
- Does it influence soft tissue formation?
- Does it alleviate post-operative pain?
- Does it improve wound healing outcomes?

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6. Hypotheses

Null Hypotheses:

- No significant difference exists between the two groups in bone resorption, bone density, soft tissue height, healing index, or pain levels.

Alternative Hypotheses:

- Significant differences exist between the two groups in one or more of the above parameters.

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7. Study Design

- Randomized controlled clinical trial using a split-mouth design.
- Allocation by draw-a-card method.

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8. Sample Size

- 12 patients (24 extraction sites), calculated using G*Power software with $\alpha = 0.05$ and power = 95%.

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9. Inclusion Criteria

- Age: 20–50 years.
- Good oral hygiene (plaque index <1, gingival index <1).
- Bilateral symmetrical teeth indicated for extraction.
- Type 1 socket (Elian et al., 2007).

Exclusion Criteria:

- Smokers, alcohol consumers.
- Pregnant or lactating women.
- Systemic diseases (e.g., uncontrolled diabetes).
- Periodontal disease or acute infection.
- Use of medications affecting bone metabolism.

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10. Methodology

Session 1:

- Clinical and radiographic examination.
- Informed consent obtained.
- Oral hygiene instructions and blood tests.

Session 2:

- Atraumatic extraction performed.
- Group 1: Sticky Bone technique using tricalcium phosphate + PRF.
- Group 2: Calcium sulfate/tricalcium phosphate (40:60 ratio).
- Post-operative medications and instructions provided.

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11. Outcome Measures

Clinical:

- Pain (VAS scale).
- Healing index (Landry et al.).

Radiographic:

- CBCT evaluation of vertical and horizontal bone changes.
- Bone density via Region of Interest (ROI) analysis.

Histological:

- Biopsy at implant placement to assess:
    - Residual graft material.
    - Inflammatory response.
    - Bone regeneration and density.
    - CD34 expression and alkaline phosphatase activity.
    - Collagen quality.

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12. Statistical Analysis

- Data analyzed using SPSS v25.
- Descriptive statistics: mean, SD, percentages.
- Inferential tests: Independent and paired T-tests, Chi-square, McNemar's test.
- Significance level: $p < 0.05$.

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13. Ethical Considerations

- Ethical approval obtained from relevant institutional review board.
- Written informed consent from all participants.
- Confidentiality and data protection ensured.
- Compliance with WHO ethical guidelines for biomedical research involving human subjects.