Study Protocol and Statistical Analysis Plan

Cover Page

Study Title: Evaluation and Treatment of Crown Fractures in Permanent Teeth Following Dental Trauma Using the Modified Baysal Dental Trauma Index and Clinical Follow-Up of Their Treatments
Brief Title: Evaluation and Treatment of Crown Fractures Using the Modified Baysal Dental Trauma Index
NCT Number: [Not yet assigned]
Unique Protocol ID: 2023/69
Date: [29.07.2025]

1. Protocol Summary

This prospective observational study aims to evaluate the clinical and radiographic outcomes of treatments applied to permanent teeth with complicated and uncomplicated crown fractures following traumatic dental injuries, using the Modified Baysal Dental Trauma Index (MB-DTI) for assessment and follow-up.

2. Objectives

Primary Objective: To evaluate treatment success based on clinical and radiographic criteria at 12 months post-treatment using the Periapical Index (PAI).

Secondary Objectives:
- To assess changes in PAI scores from baseline to 12 months.
- To compare the effectiveness of different treatment modalities (composite resin restoration, vital pulp therapy, regeneration, root canal treatment).

3. Study Design

Type: Observational, prospective cohort study
Time Perspective: Prospective
Follow-Up Duration: 12 months per participant
Number of Participants: 39

4. Study Population

Inclusion Criteria:
1. Age between 6 and 14 years
2. Presence of traumatic dental injury involving a permanent tooth
3. Type of injury classified as a complicated or uncomplicated crown fracture
4. Informed consent obtained from the patient's parent or legal guardian

Exclusion Criteria:
1. Patients younger than 6 or older than 14 years, or those presenting for non-trauma-related dental issues
2. Patients with traumatic dental injuries other than crown fractures (e.g., luxation, avulsion)

5. Sample Size Determination

The sample size was calculated based on statistical power analysis with effect size $w = 0.5$, $\alpha = 0.05$, and power $1 - \beta = 0.8$. For $df = 2$, the required total sample size was determined to be 39 participants.

6. Interventions / Treatments

Participants will receive one of the following treatments according to clinical indications:
1. Composite resin restoration
2. Vital pulp therapy
3. Regeneration procedures
4. Root canal treatment

7. Outcome Measures

Primary Outcome Measure:
Title: Proportion of Treated Teeth Without Clinical Symptoms or Radiographic Pathology at 12 Months (PAI Score ≤ 2)
Description: Treatment success will be defined as the absence of spontaneous pain, swelling, sinus tract, abnormal mobility, discoloration, and the presence of radiographic healing or absence of periapical pathology, as assessed using the Periapical Index (PAI) by Ørstavik et al. (1986). Evaluations will be performed at 12 months post-treatment.

Secondary Outcome Measure:
Title: Change in Periapical Index (PAI) Score From Baseline to 12 Months

Description: Radiographic healing will be evaluated using the PAI scoring system, comparing baseline and 12-month follow-up periapical radiographs.

8. Statistical Analysis Plan

Data will be analyzed using SPSS software.
Descriptive statistics (mean, standard deviation, frequency) will be calculated for all variables.
Comparisons between treatment groups will be performed using Chi-square test for categorical variables and independent t-test or Mann–Whitney U test for continuous variables, depending on data distribution.
Significance level will be set at $p < 0.05$.
Changes in PAI scores over time will be analyzed using the Wilcoxon signed-rank test or paired t-test as appropriate.

9. Ethical Considerations

Approval was obtained from Interventional Clinical Research Ethics Committee, Approval Number: 2023/69
Written informed consent will be obtained from the parents or legal guardians of all participants.
The study will comply with the Declaration of Helsinki principles.