STATISTICAL ANALYSIS PLAN

Study Title: Treatment Outcomes of Partial Pulpotomy Using Two Different Calcium Silicate Materials in Cariously Exposed Mature Permanent Teeth: A Randomized Clinical Trial
ClinicalTrials.gov Identifier: NCT06802549
Protocol ID: FIRATUNI-DENTISTRY-TUBAGOK-002
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Sponsor: Firat University
Principal Investigator: Tuba Gök

Transparency note: This SAP was prepared at the results-submission stage to document the planned analysis of the completed trial.

It should not be interpreted as a prospectively finalized statistical analysis plan.

1. Study Design

This study was a randomized, parallel-group clinical trial comparing partial pulpotomy performed with Biodentine and TheraCal PT in mature permanent teeth with carious pulp exposure.

A total of 61 participants were enrolled and randomized to:

- Biodentine group: n = 31
- TheraCal PT group: n = 30

Clinical and radiographic follow-up was performed for up to 12 months.

2. Study Outcomes

2.1. Primary Outcome

The primary outcome was **tooth survival/clinical and radiographic success at 12 months**.

Success was defined as survival of the treated tooth without clinical symptoms and without newly developed periapical radiolucency. Teeth requiring further endodontic treatment during follow-up were classified as treatment failures.

2.2. Secondary Outcome

The secondary outcome was **postoperative pain intensity**, evaluated using a 0–10 visual analog scale (VAS), where 0 represented no pain and 10 represented the worst possible pain.

VAS scores were recorded at:

- 6 hours
- 12 hours
- 24 hours

- 48 hours
- 72 hours
- 1 week after treatment

3. Analysis Populations

Baseline analyses will include all randomized participants.

For the 12-month primary outcome analysis, participants with available clinical and radiographic follow-up data will be included. Participants lost to follow-up will not be classified as treatment failures unless treatment failure was clinically documented before loss to follow-up.

For postoperative pain analyses, participants with available VAS measurements at the relevant assessment time will be included.

4. Descriptive Analyses

Continuous variables will be summarized using mean and standard deviation and, when appropriate, median and interquartile range.

Categorical variables will be reported as numbers and percentages.

Baseline variables will include age and sex.

No race or ethnicity data were collected.

5. Primary Outcome Analysis

The number and percentage of participants with tooth survival at 12 months will be reported separately for the Biodentine and TheraCal PT groups.

The groups will be compared using **Fisher's exact test**, because of the relatively small number of treatment failures in some cells.

Where appropriate, the between-group effect may additionally be expressed using an effect estimate such as risk difference or relative risk with a 95% confidence interval.

The primary analysis will be based on participants with available 12-month outcome data.

6. Postoperative Pain Analysis

VAS scores at each postoperative time point will be summarized as mean ± standard deviation for each treatment group.

The distribution of continuous data will be assessed using graphical methods and appropriate normality assessments.

Between-group comparisons at individual time points will be performed using an independent-samples t-test when parametric assumptions are reasonably satisfied; otherwise, the Mann–Whitney U test will be used.

Changes in postoperative pain over time may also be evaluated using an appropriate repeated-measures approach. If parametric assumptions are not satisfied, a non-parametric repeated-measures method will be considered.

Analyses of postoperative pain will be regarded as secondary/exploratory analyses.

7. Missing Data

Missing outcome data will not be replaced by fabricated or imputed clinical outcomes in the primary analysis.

Participants without a 12-month assessment will be reported as lost to follow-up and excluded from the available-case primary outcome denominator.

The number of participants analyzed at each outcome assessment will be reported.

8. Adverse Events

All-cause mortality, serious adverse events, and other adverse events will be summarized by treatment group as the number of affected participants divided by the number of participants at risk.

Postoperative pain, which was prospectively defined as a secondary study outcome, will be reported under the postoperative pain outcome rather than duplicated as an adverse event.

9. Statistical Significance

All statistical tests will be two-sided.

A **P value < 0.05** will be considered statistically significant unless adjustment for multiple comparisons is specifically required.

Exact P values will be reported whenever possible.

10. Statistical Software

Statistical analyses will be performed using an established statistical software package. The software name and version will be documented in the final analysis report/manuscript.

11. Deviations from the Analysis Plan

Any substantive deviations from this statistical analysis plan will be documented and described transparently in the final study report or publication.