Statistical Analysis Plan (SAP)

1. Study overview

This SAP describes the statistical methods for the randomized clinical study comparing SRP alone vs SRP plus adjunctive topical polyherbal phytopreparation in patients with periodontitis.

2. Objectives and endpoints

Primary endpoint: change in Gingival Index (GI) from baseline to 1 month.

Key secondary endpoint: change in Periodontal Pocket Depth (PPD) from baseline to 1 month.

Exploratory endpoints: cytomorphometric parameters (e.g., nuclear area, perimeter, Feret's diameter, integrated optical density, circularity, roundness).

3. Analysis populations

- Intention-to-treat (ITT): all randomized participants analyzed according to allocated group (preferred).
- Per-protocol (PP): participants with no major protocol deviations (supportive analysis).

4. General statistical principles

- Two-sided tests will be applied.
- Significance threshold $\alpha = 0.05$.
- Normality will be tested using Shapiro–Wilk test.
- Continuous variables summarized as mean ± SD and/or median (IQR), depending on distribution.
- Categorical variables summarized as n (%).

5. Baseline comparisons

Baseline comparability will be assessed descriptively and using appropriate tests:

- Categorical variables: Chi-square test (Mantel–Haenszel correction if required).
- Continuous variables: Student's t-test (if normal) or Mann–Whitney U test.

6. Primary endpoint analysis
Between-group comparison of GI change from baseline to 1 month will be performed using Student’s t-test (if normal) or Mann–Whitney U test (if non-normal). Within-group change will be assessed using paired t-test or Wilcoxon signed-rank test.

7. Key secondary endpoint analysis
PPD (Periodontal Pocket Depth) change will be analyzed using the same approach as for the primary endpoint.

8. Multiplicity
Multiplicity across the primary endpoint (GI) and key secondary endpoint (PPD) will be controlled using the Holm–Bonferroni procedure for between-group comparisons. Exploratory endpoints will not be adjusted and will be interpreted descriptively.

9. Effect sizes and confidence intervals
Effect sizes will be reported for primary and key secondary endpoints, including rank-biserial correlation for non-parametric comparisons where applicable. Where feasible, 95% confidence intervals will be reported.

10. Missing data
The extent and pattern of missing data will be described. For the short follow-up period, available-case analysis will be used. Sensitivity analyses may be performed if missingness is substantial.

11. Software
Statistical analyses will be performed using IBM SPSS Statistics (version 15.0 or later).