

Soft Tissue Augmentation by Xenogeneic Collagen Matrix Versus Subepithelial Connective Tissue Gr

## Statistical Analysis Plan

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## 1. Study Identification

- Protocol ID: 505/2021
- Sponsor: Minia University
- Investigator: Mohamed Omar Ismail, PhD Candidate

## 2. Study Objectives

- To compare the clinical outcomes of xenogeneic collagen matrix (XCM) and subepithelial connective

## 3. Endpoints

- Primary Endpoint: Change in peri-implant soft tissue thickness at 12 months (in mm).

## 4. Study Design Summary

- Randomized controlled trial with two parallel arms.
- 20 patients (10 per group), assigned to either SCTG or XCM group.
- Outcome assessed by a blinded evaluator.

## 5. Sample Size Justification

- Based on clinical experience and prior literature, a sample size of 10 per group was determined to

## 6. Statistical Methods

- Descriptive statistics (mean, SD) will be used for baseline characteristics.
- Independent Samples T-test will be used to compare changes in soft tissue thickness between groups.
- Significance level set at  $p < 0.05$ .
- Confidence interval: 95%

## 7. Missing Data Handling

- Missing values will be managed using pairwise deletion. No imputation methods are planned.

## 8. Software to be Used

- Statistical analysis will be conducted using SPSS version 25 (IBM Corp.).

## 9. Data Presentation

- Data will be presented in tables (means  $\pm$  SD).
- Results will be illustrated using bar charts to compare primary outcomes.