

ISRCTN registry: Analysis of the pulpal blood flow microdynamics during prosthetic tooth preparation using diamond burs with different degrees of wear

Statistical analysis plan

Sample size

Necessary sample size was determined based on the mixed factorial designed combining the between-group treatment factor with the within-subject variable of repeated measures in time. The research focused on the change in the mean blood flow value, so the necessary sample size was decided based on this expected effect size and a balanced two-way ANOVA model. For the experimental model with two treatments and at least five patient groups, the necessary size resulted in three teeth in each group, leading to the required total of at least 30 teeth in the sample ($\alpha = 0.05$; $\beta = 0.2$; Cohen's d effect size was equal to 0.8 for both treatment and within-subject factors). To account for potential dropouts, a sample size of six patients and 32 teeth was decided.

The sample size was determined with the R 4.2.2 package "pwr" version 1.3

Randomization was single-blind and performed with the R 4.2.2 package "blockrand" version 1.5.

Data analysis

Normality of numerical variables was tested with Kolmogorov-Smirnov statistical test; their descriptive statistics comprised the mean $\pm$ standard deviation. Four-way ANOVA was used for analysis: pulp blood flow values (numerical variable) and four factors (categorical variables). The factors were: degree of bur wear (two wear levels), time of measurement (four measurements), tooth location (upper or lower jaw), tooth number (1, 2, and 3). Post-hoc comparisons were conducted according to the Tukey procedure.

The statistical analysis was conducted at a 95% level of confidence (i.e. 5% level of statistical significance). All reported probability values were two-tailed, and statistical significance was explicitly marked.

Data were analyzed with the statistical software IBM SPSS version 20.0 and R version 4.2.2.