

Title: Clinical and Radiographic Evaluation of Formocresol, Ferric Sulfate and Hyaluronic Acid Pulpotomies on Human Primary Teeth: A Randomized Controlled Clinical Trial

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Study Protocol and Statistical Analysis Plan

In this study, 120 primary molar teeth from healthy children aged between 5 and 9 and who apply to Marmara University Faculty of Dentistry Department of Pediatric Dentistry will be subjected to pulpotomy treatments. Ethical approval of the study was obtained from the Clinical Research Ethics Committee, Faculty of Dentistry at Marmara University (No: 2019/288) in accordance with the Declaration of Helsinki. Sample size calculation showed that at first 40 teeth in each group will be required to detect a significant difference (80% power, two-sided 5% significance level). After proper diagnosis of coronal pulpitis, the teeth will be assigned randomly to one of the 3 groups: 40 primary molars for formocresol pulpotomy treatments, 40 primary molars for ferric sulfate treatments and 40 primary molars for 0.5% hyaluronic acid gel pulpotomy treatments. The tooth decay will be removed, the pulp will be amputated from the chamber of the pulp with a sharp excavator and one of the medicament will be applied to the orifice of the root canals. The cavity will be sealed tight with zinc oxide cement and the primary molars will be restored either with a composite filling material in case of occlusal cavities or with a stainless-steel crown in case of proximal cavities. A single investigator will perform the procedure. The teeth will be followed clinically and radiographically at 1st, 3rd, 6th, 12th months.

Statistical analyzes in this study will be performed using the NCSS (Number Cruncher Statistical System) 2007 Statistical Software (Utah, USA) packaged software. In the evaluation of the data, in addition to descriptive statistical methods (mean, standard deviation, frequency and percentage distributions), the distribution of variables will be examined with the Shapiro-Wilk normality test, the independent t test for the comparison of the normally distributed variables in binary groups, the chi-square and Fisher exact test for the comparison of qualitative data, Mc Nemar's test will be used for time comparisons of qualitative data. The results will be evaluated at the significance level of $p < 0.05$.