Statistical Analysis Plan (SAP)

Comparative evaluation of the effectiveness of root canal preparation after irrigation using endodontic needle and inertial cavitation: A randomized controlled trial

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1. Introduction

The primary objective of this randomized controlled trial is to compare the postoperative pain intensity levels in patients with asymptomatic teeth diagnosed for non-surgical orthograde root canal treatment that are disinfected during the root canal treatment procedure by manual irrigation with sodium hypochlorite (NaOCl) solution or EndoClean. The null hypothesis is that there will not be a significant difference in postoperative pain intensity levels between patients who will undergo root canal treatment with manual irrigation with NaOCl or EndoClean.

This statistical analysis plan (SAP) will give more detailed descriptions of the endpoints in the study and the corresponding analyses.

2. Study Design

The protocol of this prospective, 2-arm, randomized controlled clinical trial and consent forms for the patients will be approved by the ministry of health and ethics committee of the university. The study will be registered on www.clinicaltrials.gov. The study will be following the Consolidated Standards of Reporting Trials (CONSORT) guidelines **(Moher *et al*. 2010)**. All patients will be informed about the nature of the study, the treatment procedures, evaluation process, benefits, and the potential risks before they will be asked to sign a written consent form. The enrolment of patients will be executed from the outpatient clinic of Department of Endodontics, Faculty of Dentistry, Istanbul Medipol University, Turkey.

2.1. Sample Size Calculation

In order to determine the number of samples, power analysis was performed using the G*Power (v3.1.9.2) program. The power of the study is expressed as 1-β (β = probability of type II error). Based on the postoperative 6th-hour pain measurements in the article by D. Liapis et al.*, the mean for Group I was 13.9 SD:16.2; When the mean for Group II was taken as 4.9 SD: 7.3, the effect size (d) was found to be 0.716 in the calculation made to obtain 90% power at the α=0.05 level. Accordingly, it was calculated that there should be at least 42 people in each group and 84 people in total. Considering that there may be losses during the study process (20%), it was decided to take at least 50 people in each group.

10 patients will be involved in a pilot study. There will be 5 patients in each group: manual final irrigation and EndoClean device. Pilot study will be conducted for two reasons. The first reason is to ensure the safety of the device for clinical use. The second reason is to conduct an accurate power analysis and therefore, a sample group for the full clinical study. A full clinical investigation will be performed once the pilot study is done, and which will be powered according to the outcome of the pilot study.

3. Objectives

The primary objective of this randomized controlled trial is to compare the postoperative pain intensity levels in patients with asymptomatic teeth diagnosed for non-surgical orthograde root canal treatment that are disinfected during the root canal treatment procedure by manual irrigation with

sodium hypochlorite (NaOCl) solution or EndoClean. The secondary objective is to evaluate, if EndoClean could be used safely during root canal treatment as an alternative approach to manual irrigation.

4. Outcomes

4.1 Primary Outcome:

All participants will be asked to grade their pain intensity level on a horizontal Visual Analogue Scale (VAS) before the treatment procedure. This scale is a horizontal 100 mm bar, marked in every 10mm with two ends. One end (0) indicated “no pain” and the other end (10) indicated “worst pain possible”. Categorization of pain scores is as follows: 0-4 mm = No Pain, 5-44 mm = Mild Pain, 45-74 mm = Moderate Pain, 75-100 mm = severe pain. After grading the pain level, the distance between the marked point and the “no pain” endpoint will be measured with a ruler to calculate the pain intensity level. Clinical and radiological findings consistent with the asymptomatic tooth with nonvital pulp tissue with the preoperative pain intensity scores in the category of “no pain” will be included in the study.

4.2 Secondary Outcome:

If excessive pain will be experienced by three concomitant patients the study will be terminated.

5. Populations to be Analysed

Data of all randomised study subjects will be analysed. This will be seen as the primary population for the analysis. For any specific analysis, study subjects with missing data on any of the variables in the model will be excluded from the analysis.

6. Analyses

All outcomes will be presented using descriptive statistics; normally distributed data by the mean and standard deviation (SD) and skewed distributions by the median and interquartile range (IQR). Binary and categorical variables will be presented using counts and percentages. Python programming language and its dependent statical libraries will be used for all statistical analysis.

The subsections below will describe analyses in addition to the descriptive statistics.

6.1 Outcome

The primary analysis will compare the treatment groups [EndoClean and manual irrigation with sodium hypochlorite (NaOCl)] on their mean difference in post-operative pain sensitivity throughout a week period (6h, 24h, 48h, 72h and 1w). Declared pain scores over time for the patients will be the dependent variable. Study subjects will be considered as random effects, treatment group and visit number as fixed effects. Other variables like Age and Toot-ID can be included as a covariate according to their relations with response variable. The estimated difference in mean change from EndoClean and Control groups and the corresponding 95 % confidence interval (CI) will be presented.