Official Title:
Pain Management in Teeth with Reversible Pulpitis: A Randomised Controlled Trial

NCT Number:
Pending

Document Date:
August 2, 2025

RESULTS

Note: This study protocol outlines a planned clinical trial. As of the document date (August 2, 2025)

STUDY PROTOCOL AND STATISTICAL ANALYSIS PLAN

Study Title: The Effect of Preoperative Ibuprofen Administration on Pain During Vital Pulp Therapy in Children Diagnosed with Reversible Pulpitis: A Randomized Controlled Trial

Document Type: Study Protocol and Statistical Analysis Plan

Investigator: Dr. Merve Bilmez Selen

Institution: Inönü University Faculty of Dentistry

Date: July 25, 2025

NCT Number: Pending

Note: This document is submitted for public posting in ClinicalTrials.gov.

STUDY PROTOCOL

1. Introduction

Pain experienced during dental procedures is a major factor negatively affecting cooperation in pediatric patients. In cases of reversible pulpitis, preoperative use of analgesics during vital pulp therapy (VPT) may contribute significantly to pain management.

2. Objective

The aim of this study is to evaluate the effect of preoperative ibuprofen administration on intraoperative pain and physiological stress in children undergoing VPT on mandibular first permanent molars diagnosed with reversible pulpitis.

3. Hypothesis

Preoperative administration of ibuprofen will significantly reduce intraoperative pain levels.

4. Methods

- Design: Prospective, randomized, controlled clinical trial

- Setting: Department of Pediatric Dentistry, Faculty of Dentistry, Inönü University

- Participants:

• Age: 7–13 years

• Condition: Reversible pulpitis in mandibular first permanent molars

• Sample size: 44 patients (22 intervention, 22 control)

- Randomization: Computer-generated random sequence using sealed-envelope method

- Blinding: Single-blind (statistician blinded)

- Intervention:

• Intervention group: Oral ibuprofen (10 mg/kg) 40 minutes before treatment

• Control group: No preoperative medication

- Anesthesia: Inferior alveolar nerve block (articaine HCl 4% with epinephrine 1:100,000)

5. Procedure and Follow-up

VPT will be performed (direct pulp capping, partial or total pulpotomy as appropriate). Intraoperative pain will be assessed using the Visual Analogue Scale (VAS). Pulse rate will be monitored using a fingertip pulse oximeter. Postoperative pain will be assessed using VAS on Days 1, 3, and 7.

6. Ethical Approval

Ethical approval for this study was obtained from the Inönü University Clinical Research Ethics Committee (Approval No: 2024-KAEK-08; Date: December 25, 2024). Written informed consent will be obtained from the legal guardians of all participants. The study will be conducted in accordance with the Declaration of Helsinki.

7. Timeline

• Enrollment: July 2025

• Data collection: July–August 2025

• Primary completion date: Estimated August 2025

STATISTICAL ANALYSIS PLAN

1. Objective

This statistical analysis plan aims to outline the methodology for analyzing the effect of preoperative ibuprofen administration on intraoperative pain (measured using the Visual Analogue Scale – VAS) and physiological stress (measured via pulse rate variation) in children undergoing vital pulp therapy (VPT) for reversible pulpitis.

2. Sample Size Calculation

The required sample size was determined using G*Power software (version 3.1) with the following parameters:

- Effect size (Cohen’s d): 0.8

- Power: 80%

- Alpha (Type I error): 0.05

- Minimum required participants: 22 per group

3. Descriptive Statistics

- Continuous variables (e.g., age, VAS scores, pulse rates) will be expressed as mean ± standard deviation (SD)

- Categorical variables (e.g., sex) will be presented as frequency and percentage

4. Normality Testing

The Shapiro–Wilk test will be used to assess the normality of continuous data distributions.

5. Comparative Analyses

- Between-group comparisons:

• For normally distributed data: Independent samples t-test

• For non-normally distributed data: Mann–Whitney U test

- Within-group comparisons (e.g., pulse change): Wilcoxon signed-rank test

- Longitudinal analysis of postoperative pain (Days 1, 3, and 7): Friedman test

- Subgroup analyses:

• Sex-based and apex closure status comparisons using Mann–Whitney U test

- Correlation analyses:

• Spearman’s rank correlation coefficient to assess the relationship between pulse change and VAS scores, and between age and pain scores

6. Statistical Significance

A p-value < 0.05 will be considered statistically significant.

7. Software

All analyses will be conducted using IBM SPSS Statistics for Windows, version 27.0 (IBM Corp., Armonk, NY, USA).