12.07.2025

STUDY PROTOCOL

Evaluation of the effects of syringe-based and computer-controlled local anesthesia systems and different anesthetic agents on pain and anxiety in pediatric dental patients

The study was approved by the Medical Ethics Committee of Harran University with report number HRÜ/25.06.54.

This randomized controlled clinical trial will be conducted at the Department of Pediatric Dentistry, Faculty of Dentistry, Dicle University, located in Diyarbakır, Turkey. A total of 84 voluntary pediatric patients aged between 7 and 10 years who meet the defined eligibility criteria will be included in the study. These patients will be selected from those with primary molars requiring pulpotomy or pulpectomy treatment located in either the maxilla or mandible.

Before any intervention, patients and their legal guardians will be fully informed about the study, and written informed consent will be obtained. The aim of this study is to evaluate and compare the effects of traditional local anesthesia techniques and computer-controlled local anesthesia systems (SleeperOne® – intraosseous anesthesia) on children's pain and anxiety levels.

According to a within-subject crossover design, both traditional (syringe-based) and computer-controlled anesthesia methods will be applied to the same patient, but on different sides of the mouth. This design allows for objective comparisons and minimizes inter-individual variability. A total of 42 patients will be included in each group, with each child serving as their own control. Local anesthesia will be administered to the teeth on either the left or right side depending on clinical indication.

Primary and secondary outcome measures will include assessments of both physiological and psychological parameters. Pain and anxiety levels will be evaluated using a combination of psychometric, physiological, and biochemical methods. The measurements will include:

Physiological Measurements:

- Heart rate (bpm)
- Oxygen saturation (SpO_2)
- Body temperature (°C)

Psychometric Scales:

- Facial Image Scale (FIS)
- Visual Analog Scale (VAS)

- Wong-Baker Faces Pain Rating Scale (WBS)
- Modified Child Dental Anxiety Scale (MCDAS)
- Children’s Fear Survey Schedule – Dental Subscale (CFSS-DS)
- FLACC Behavioral Pain Assessment Scale (Face, Legs, Activity, Cry, Consolability)

The data obtained from these assessments will be recorded for both groups and statistically analyzed to determine which local anesthesia technique is more effective in reducing pain and anxiety.

Additionally, the heart rate, oxygen saturation, and body temperature of the operator performing the procedure will also be measured to evaluate the impact of digital and traditional anesthesia techniques on the dentist's stress and anxiety levels.

Patient Evaluation Form

Patient Information

Patient Name / Surname:	
Protocol No:	
Phone number	
Age / Sex:	
CFSS-DS Score: (measured only once, first visit)	
Operated Area: Maxilla or Mandible	

Visit 1 – Traditional or Digital Anesthesia

Measurements Patients (Before / During / After)

Measurement	Before	During	After
Pulse Rate (bpm)			
Oxygen Saturation (%)			
Body Temperature (°C)			

Measurements Patients (Before / After)

Measurement	Before	After
Wong-Baker Score (WBS)		
Facial Image Scale (FIS)		

Measurements Patients (During only)

Measurement	During
Visual Analog Scale (VAS)	
FLACC Scale	

Measurements – Operator

Measurement	Before	During	After
Pulse Rate (bpm)			
Oxygen Saturation (%)			
Body Temperature (°C)			

Visit 2 – Traditional or Digital Anesthesia

Measurements Patients (Before / During / After)

Measurement	Before	During	After
Pulse Rate (bpm)			
Oxygen Saturation (%)			
Body Temperature (°C)			

Measurements Patients (Before / After)

Measurement	Before	After
Wong-Baker Score (WBS)		
Facial Image Scale (FIS)		

Measurements Patients (During only)

Measurement	During
Visual Analog Scale (VAS)	
FLACC Scale	

Measurements – Operator

Measurement	Before	During	After
Pulse Rate (bpm)			
Oxygen Saturation (%)			
Body Temperature (°C)			

Statistical Analysis

The statistical analysis of the research data will be conducted using IBM SPSS Statistics for Windows, Version 21.0. Continuous variables will be presented as mean ± standard deviation (SD), median, minimum value, maximum value, correlation coefficient (r), coefficient of variation (CV%), 95% confidence interval (95% CI), consistency rate, and weighted kappa (κ). Categorical variables will be expressed as numbers and percentages (%). The Kolmogorov-Smirnov test will be used to assess the normality of data distribution.

For data with normal distribution, comparisons between two groups will be performed using the Independent Samples t-test. For non-normally distributed data, the Mann-Whitney U test will be used for comparisons involving two groups. Repeated Measures ANOVA will be applied for comparisons among more than two groups.

For categorical data, intergroup comparisons will be performed using the Pearson Chi-square (χ^2) test, Yates-corrected Chi-square (χ^2) test, Fisher's exact test, McNemar test, Kendall's W test, and Cochran's Q test (for k-related samples), as appropriate.

The relationship between variables will be evaluated using Pearson or Spearman correlation analysis. Additional statistical analyses will be conducted if necessary. All hypotheses will be tested two-tailed, and a p-value ≤ 0.05 will be considered statistically significant.

INFORMED CONSENT FORM FOR PARENTS (ICFP)

STUDY TITLE:

Evaluation of the effects of syringe-based and computer-controlled local anesthesia systems and different anesthetic agents on pain and anxiety in pediatric dental patients

You are being invited to allow your child to participate in a research study. Participation in this study is entirely voluntary. Before you decide whether to participate, it is important that you understand why the research is being conducted and what it involves. This includes how your and your child's information will be used, what procedures are involved, as well as any potential benefits, risks, or discomforts. Please take the time to read the following information carefully.

If you agree to participate, please sign the Consent to Participate form at the end. You are free to withdraw from the study at any time without penalty.

You will not receive any financial compensation for participation, nor will you be asked to make any financial or material contribution. All materials and costs related to the study will be covered by the researchers.

STUDY OBJECTIVE:

One of the greatest sources of fear in pediatric dental patients is the local anesthesia procedure, which significantly affects the acceptance of dental treatment.

This study aims to evaluate the effects of different anesthetic agents administered via a computer-controlled anesthesia system (SleeperOne® – intraosseous anesthesia) and conventional local anesthesia techniques on pain and anxiety levels in children.

STUDY PROCEDURES:

Children who require dental treatment on either the left or right side of the jaw and meet the inclusion criteria will be included in this study.

Both conventional local anesthesia and computer-controlled local anesthesia using the SleeperOne® (CCLAD) system will be applied to the same patient.

Various devices, questionnaires, and analyses will be used to measure pain and anxiety levels for both techniques.

POTENTIAL BENEFITS OF PARTICIPATION:

Although your child may not directly benefit from participation, the data collected may contribute to scientific knowledge and benefit other children in similar situations.

HOW WILL PERSONAL INFORMATION BE USED?

No identifying personal information will be used other than the child's age and gender.

CONTACT INFORMATION FOR QUESTIONS AND CONCERNS:

- Prof. Dr. Emin Caner TÜMEN – 0533 264 69 33
- Res. Assist. Dt. Hasan Said ŞENER – 0530 150 73 94
- Res. Assist. Dt. Merve GÜNGÖR – 0530 155 63 58

Consent to Participate

I have discussed the details of this study with the relevant researcher and all my questions have been answered satisfactorily.

I have read and understood this informed consent document. I voluntarily agree to allow my child to participate in this research study.

I understand that this consent does not override any applicable laws or regulations.

The researcher has provided me with a copy of this consent form, including instructions on points to be considered during the study.

Parent/Guardian Full Name:

Date and Signature:

Phone Number:

Legal Guardian (if applicable):

Full Name:

Date and Signature:

Phone Number:

Researcher's Full Name:

Date and Signature:

Address and Phone Number:

INFORMED ASSENT FORM FOR CHILD VOLUNTEERS (IACF)

STUDY TITLE:

Evaluation of the effects of syringe-based and computer-controlled local anesthesia systems and different anesthetic agents on pain and anxiety in pediatric dental patients

STUDY OBJECTIVE:

One of the greatest sources of fear in pediatric dental patients is the local anesthesia procedure, and acceptance of dental treatment is largely dependent on overcoming this fear.

This study aims to evaluate the effects of different anesthetic agents applied using a computer-controlled anesthesia system (SleeperOne® - intraosseous anesthesia) and conventional local anesthesia on pain and anxiety levels in children.

STUDY PROCEDURES:

Children who have treatment-needing teeth on either side of the jaw and meet the research criteria will be included in the study. Both conventional local anesthesia and the SleeperOne® computer-controlled local anesthesia system (CCLAD) will be applied to the same patient. Various devices, questionnaires, and analyses will be used to measure pain and anxiety levels in both procedures.

WHAT ARE THE POTENTIAL BENEFITS OF PARTICIPATION?

The information obtained from you and children in similar situations will contribute to scientific knowledge.

HOW WILL MY PERSONAL INFORMATION BE USED?

Only your age and gender will be used. No other personal identifying information will be collected or used.

CONTACT INFORMATION FOR QUESTIONS AND CONCERNS:

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Assent to Participate

Before deciding to take part in this study, you should talk to your mom and dad and ask their opinion. We will also ask for their permission. Even if they say yes, you can still say no. It is your choice whether you want to be in the study or not. If you say no, nobody will be upset or angry with you.

Even if you agree now, you can change your mind later. That’s okay too. If you decide not to participate, your doctors will still treat you just the same as always.

If you have any questions now or later, you can ask me at any time. My phone number and address are written on this paper. If you want to be in this study, please write your name and sign below. You and your parents will get a copy of this form after you sign it.

Child Volunteer Full Name:

Date and Signature:

Phone Number:

Parent/Guardian Full Name:

Date and Signature:

Phone Number:

Researcher's Full Name:

Date and Signature:

Address and Phone Number:

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Date and Signature:

Phone Number:

Legal Guardian (if applicable):

Full Name:

Date and Signature:

Phone Number:

Researcher's Full Name:

Date and Signature: