National and Kapodistrian University of Athens

School of Health Sciences — Department of Dentistry

Informed Consent Form

A Randomized Controlled Trial of the Acceptance of Two Computer-Controlled Anaesthetic Delivery Systems in Paediatric Patients

Brief Title:	Wand STA vs SleeperOne for Pediatric Local Anesthesia (WASO-Kids)
NCT Number:	NCT ID not yet assigned
Unique Protocol ID:	634/26.02.2024
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HELLENIC REPUBLIC
National and Kapodistrian University of Athens
(Founded 1837)

School of Health Sciences
Department of Dentistry
Research Ethics and Deontology Committee

Informed Consent Form for Research Participation

Research Program Number: …… (left blank if this is a new application)

Title of Research Program: Randomized clinical trial of the acceptance of two electronic dental local anesthesia systems in pediatric dental patients.

School/Department: Postgraduate Clinic of Pediatric Dentistry, School of Dentistry, National and Kapodistrian University of Athens

Principal Investigator: Andreas Agouropoulos, Assistant Professor, NKUA, Tel: 210 746 1219, agourop@dent.uoa.gr

Co-investigator: Sotiria Gizani, Associate Professor and Director of the Pediatric Dentistry Laboratory, NKUA, Tel: 210 746 1253, stgizani@dent.uoa.gr

Co-investigator: Viktoria Eustratia Katechi, Postgraduate Student, Tel: 6932322991, victoriakatechi@hotmail.com

You are being asked to participate in a research program supported by the National and Kapodistrian University of Athens (NKUA). The following information is provided so that you can decide whether you wish to participate.

1. Purpose

The purpose of this study is to evaluate the acceptance of two electronic anesthesia systems used in children.

2. Procedures

Participation in this research involves the scheduled dental treatment, during which local anesthesia will be administered using two different electronic anesthesia devices, one per session. After each local anesthesia procedure, patients will be asked to rate their discomfort during the procedure.

3. Exclusions

You cannot participate in this research if any of the following applies to you: you are older than 9 years or younger than 4 years of age; you have health problems; or you have taken pain medication in the preceding 12 hours.

4. Risks and Discomforts

There are no further risks associated with your participation in this study beyond the sensation that follows local anesthesia.

5. Cost of Research

No additional cost beyond the standard fees of the Department of Dentistry is anticipated.

6a. Benefits

The benefit of your participation in this research is the key advantage of electronic anesthesia systems: anesthesia is delivered in a less painful manner.

6b. Payment

No payment will be made for your participation in this research.

7. Alternatives

An alternative option is the use of conventional dental anesthesia.

8. New Findings

Any new information that becomes available during the course of the research and that may affect your decision to continue participating will be explained to you.

9. Confidentiality

Full confidentiality will be maintained for all records. However, there is no guarantee that this information cannot be disclosed in court or other legal proceedings. Even in such a case, your name and surname will not be mentioned in any report or publication.

10. Limited Institutional Liability

All research carries risks, which may include physical harm. Despite all precautions, complications may arise from your participation in the research. Should such complications occur, the investigators will assist you by arranging appropriate medical or dental treatment, but the associated cost will be charged to you or your insurance provider. NKUA has no budget for compensation in the event of physical harm, complications, or related medical treatment. By signing this form, however, you do not waive your legal rights.

11. Right to Non-Participation or Withdrawal

You may withdraw from the program at any time. Your withdrawal does not affect your ability to receive treatment from the Department of Dentistry or any other benefits you are entitled to, nor does declining to participate affect your ability to receive treatment from the Department of Dentistry or other benefits. The principal investigator has the right to terminate your participation at any time, whether due to an unexpected reaction on your part, failure to follow instructions, or termination of the study as a whole.

12. Assurance that Questions Have Been and Will Be Answered

If you have further questions about the research, you may contact the principal investigator, Andreas Agouropoulos, Assistant Professor NKUA, Tel: 210 746 1219, agourop@dent.uoa.gr. This program has been reviewed and approved by the Research Ethics Committee of the Department of Dentistry, NKUA. Questions concerning the Committee may be directed to the Department Chair at 210 746 1114, via Ms. E. Koumoutsea.

I have read the above information and I agree to participate in the research. I understand that I will receive a copy of this consent form once it has been signed.

Athens, …. / …. / 20…

Participant in the Research Program

(Full name, signature) _____

(In the case of a minor under 18 years of age)

Person exercising parental authority / custody / legal guardianship

(Full name, signature) _____

Researcher who obtained consent

(Full name, signature) _____