

Comparison of a computer-controlled bone anaesthesia delivery system the versus conventional anaesthesia in child dental patients

Submission date 10/01/2026	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 14/01/2026	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 14/01/2026	Condition category Oral Health	☐ Individual participant data ☒ Record updated in last year

Plain English summary of protocol

Plain English summary of protocol not provided at time of registration.

Contact information

Type(s)

Principal investigator, Scientific, Public

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Additional identifiers

Study information

Scientific Title

Comparison of computer controlled intraosseous anaesthesia and conventional anaesthesia in paediatric dental patients. A randomised controlled trial

Study objectives

This is a randomised controlled split-mouth comparison of the efficacy, acceptance and preference of computer-controlled intraosseous anaesthesia and conventional local anesthesia for paediatric dental patients.

Ethics approval required

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Ethics approval(s)

Approved 01/10/2020, Bio-Ethics Committee of the School of Dentistry, Aristotle University of Thessaloniki, Greece (Aristotle University of Thessaloniki GR 54124, Thessaloniki Greece, Thessaloniki, 54124, Greece; +32310999652; econom@dent.auth.gr), ref: 93/01-10-2020

Primary study design

Interventional

Allocation

Randomized controlled trial

Masking

Open (masking not used)

Control

Active

Assignment

Parallel

Purpose

Treatment

Study type(s)

Health condition(s) or problem(s) studied

Comparison of the efficacy, acceptance and preference of computer controlled intraosseous anaesthesia and conventional local anesthesia for paediatric dental patients.

Interventions

Healthy children aged 5-9 years old requiring similar treatment in both sides of the upper or the lower jaw are recruited in the Paediatric Dentistry Department of Dental School of Aristotle University of Thessaloniki, Greece, and randomized with split-mouth design to intraosseous anesthesia with Quicksleeper 5® (Dental HiTec, Cholet, France) on one side and conventional local anesthesia to the other side, with one week between them. The side as well as the order of administration are randomly assigned. A single experienced paediatric dentist is applying both methods and data collection. Patients are asked questions to assess their acceptance/preference for the two methods. Data are analyzed statistically with linear/logistic regressions at $\alpha=5\%$.

Intervention Type

Procedure/Surgery

Primary outcome(s)

1. Efficacy, acceptance and preference, child cooperation measured using the Frankl scale for child cooperation, treatment completion recorded as completed or not completed, acceptance and preference were assessed using questionnaires at during anaesthetic administration, immediately after administration, on a third appointment after a week from the last administration

Key secondary outcome(s)**Completion date**

28/09/2024

Eligibility**Key inclusion criteria**

1. Healthy children aged 5-9 years
2. Cooperative children, Frankl scale 3 or 4
3. Patients should require two bilateral similar dental treatments in homologous teeth
4. Patient should require one third treatment requiring dental anaesthesia

Healthy volunteers allowed

Yes

Age group

Child

Lower age limit

5 Years

Upper age limit

9 Years

Sex

All

Total final enrolment

64

Key exclusion criteria

1. Unhealthy
2. Uncooperative (Frankl 1 or 2)
3. Not eligible for split-mouth design

Date of first enrolment

20/06/2023

Date of final enrolment

28/09/2024

Locations

Countries of recruitment

Greece

Sponsor information

Organisation

Aristotle University of Thessaloniki

ROR

<https://ror.org/02j61yw88>

Funder(s)

Funder type

Funder Name

Aristotle University of Thessaloniki

Alternative Name(s)

Aristotelian University, University of Thessaloniki

Funding Body Type

Private sector organisation

Funding Body Subtype

Universities (academic only)

Location

Greece

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Data sharing statement to be made available at a later date