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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

Registration date
14/01/2026

Overall study status
Completed

Last Edited
09/11/2026

Condition category
Oral Health

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] 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
Ethics approval required

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: 94/01-10-2020

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