

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

Evaluation of the effect of local anesthesia for dental treatment of children under general anesthesia on physiologic parameters of the patient and on recovery of the patients

Protocol summary

Study aim

Evaluation of the effect of local anesthesia for dental treatment of children under general anesthesia on physiologic parameters of patient and on recovery of the patients

Design

A clinical trial with a parallel intervention group, double-blind, randomized, random sampling method. 142 patients undergoing general anesthesia under dental treatment (71 patients with local anesthesia during treatment and 71 without it) will be included in the study. After treatment, physiological parameters are recorded in both groups. Also, the duration of postoperative recovery and postoperative pain is assessed by the Alderete criterion.

Settings and conduct

This study will be performed in the pediatric ward of Tehran Dental School. Seventy-one children in need of dental treatment under anesthesia will be injected with anesthesia, and another 71 will not inject with anesthesia. After treatment, clinical symptoms, pain, and recovery time will be recorded. The evaluator and participant in the study are not aware of the type of treatment.

Participants/Inclusion and exclusion criteria

Inclusion: Children who are medically in the ASA I or ASA II category. Children need anesthesia treatment according to the initial examination for dental treatment. Children need pulp therapy and dental veneers in the maxilla. Exclusion: The child or his / her parents are not satisfied with participating in the study. Children with certain medical conditions, such as any systemic disease such as heart disease, kidney disease, allergy to local anesthetics, etc.

Intervention groups

The intervention group included children who were candidates for general anesthesia undergoing dental

treatments and underwent local anesthesia during treatment. The control group included children who were not under local anesthesia during treatment.

Main outcome variables

Physiological parameters, recovery time, and amount of pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220425054651N1**

Registration date: **2022-04-29, 1401/02/09**

Registration timing: **prospective**

Last update: **2022-04-29, 1401/02/09**

Update count: **0**

Registration date

2022-04-29, 1401/02/09

Registrant information

Name

Mohammad Hassan Hamrah

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4279 4500

Email address

hassanhamrah@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-05, 1401/02/15

Expected recruitment end date

2022-06-04, 1401/03/14

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the effect of local anesthesia for dental treatment of children under general anesthesia on physiologic parameters of the patient and on recovery of the patients

Public title
The effect of local anesthesia for dental treatment of children on physiologic parameters of patients

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Children who are medically in the ASA I or ASA II category. Children need anesthesia treatment according to the initial examination for dental treatment. Children need pulp therapy and dental veneers in the maxilla.
Exclusion criteria:
 The child or his / her parents are not satisfied with participating in the study. Children with certain medical conditions, such as any systemic disease such as heart disease, kidney disease, allergy to local anesthetics, etc.

Age
From **3 years** old to **12 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **142**

Randomization (investigator's opinion)
Randomized

Randomization description
Candidate children for general anesthesia undergoing dental treatment referred to Tehran Dental School will be randomly divided into two intervention groups (local anesthesia during dental treatment) and the control group (without local anesthesia during dental treatment) by the size 43 permutation block method.

Blinding (investigator's opinion)
Double blinded

Blinding description
The present study is two-way blind, and the outcome assessor, data analyst, and study participant are not aware of the type of intervention. The outcome researcher and evaluator are unaware of the randomization of patients to the two groups receiving

local anesthesia and not receiving local anesthesia and do not intervene. Vials containing local anesthesia and vials without local anesthesia are prepared in advance by an operating room nurse who is not involved in collecting, analyzing, and evaluating the outcome.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
 Ethics Committee of Tehran University of Medical Sciences
Street address
 Central office of Tehran University of Medical Sciences, Ghods St, Keshavarz Blvd
City
 Tehran
Province
 Tehran
Postal code
 1417653761
Approval date
 2021-10-30, 1400/08/08
Ethics committee reference number
 IR.TUMS.DENTISTRY.REC.1400.159

Health conditions studied

1

Description of health condition studied
 Dental root caries
ICD-10 code
 K02.7
ICD-10 code description
 Dental root caries

Primary outcomes

1

Description
 Heart rate
Timepoint
 Immediately after the start of pulpotomy treatment, at the moment of chamber pulp entry, at the end of coronary pulp removal, and the completion of pulpotomy treatment.
Method of measurement
 Heart rate recorder

2

Description

Arterial blood pressure

Timepoint

Immediately after the start of pulpotomy treatment, at the moment of chamber pulp entry, at the end of coronary pulp removal, and the completion of pulpotomy treatment.

Method of measurement

Mercury barometer

3

Description

Arterial oxygen saturation level

Timepoint

Immediately after the start of pulpotomy treatment, at the moment of chamber pulp entry, at the end of coronary pulp removal, and at the completion of pulpotomy treatment.

Method of measurement

Arterial oxygen measuring device

4

Description

End-tidal CO₂

Timepoint

Immediately after the start of pulpotomy treatment, at the moment of chamber pulp entry, at the end of coronary pulp removal, and at the completion of pulpotomy treatment.

Method of measurement

End-tidal CO₂ recorder

5

Description

Recovery time

Timepoint

After surgery

Method of measurement

Time elapsed (minutes)

6

Description

The amount of pain

Timepoint

After recovery

Method of measurement

Alderete Index

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Children who need dental treatment under general anesthesia and receive local anesthetic lidocaine 2% epinephrine 1: 100,000 at 3 minutes before the start of treatment. They are then treated with a pulpotomy. Physiological parameters and recovery time, and patients' pain are measured and recorded during and after treatment.

Category

N/A

2

Description

Control group: Children who need dental treatment under general anesthesia. They are then treated with a pulpotomy. Physiological parameters and recovery time, and patients' pain are measured and recorded during and after treatment.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of Periodontics, School of Dentistry, Tehran University of Medical Sciences and Health Se

Full name of responsible person

Ali Baghalian

Street address

School of Dentistry, Tehran University of Medical Sciences, North Karegar St, Tehran-Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Ahmadreza Shamshiri

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arshamshiri@tums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Ali Baghalian

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to
make this available
Data Dictionary

Undecided - It is not yet known if there will be a plan to
make this available