Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Sep 2026

Evaluation of Physiologic and non physiologic Effects of Two Adjacent Primary Molars Treatment in One Single Session in5-7 years old children

Protocol summary

Study aim
Different Aspects of Two Adjacent Primary Molars Treatment in One Single In-dental school

Design
Clinical trial, double-blind, randomized, on 58 patients, randomized block method is used for randomization.

Settings and conduct
The study will be perfumed in year 1402 in the pediatric department of zahedan Dental school, double-blind is perfumed for patients and evaluator.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Children aged 5-7 years without any physical or mental illnesses, cooperation based on the Frankl behavior rating scale (Frankl 3 or 4), candidates for routine dental treatment at the clinic for the first time, having at least four asymptomatic decayed primary molars requiring pulpotomy and stainless steel crown (SSC), with at least three of them in one jaw. Exclusion Criteria: Children with a history of unfavorable medical or dental conditions, dental emergencies, tooth pain except for food impaction, systemic illness or medication intake, known allergies or contraindications to the anesthesia solution, requiring pharmacological behavior management techniques, unusual bleeding during pulp exposure or pulp chamber removal, requiring complete pulpal anesthesia, non-cooperative children (Frankl 1: definitely negative)

Intervention groups
Intervention group: treatment of two adjacent molars in a child and investigation of its physiological and non-physiological effects (experimental arc). Control group: treatment of a single molar tooth and investigation of the physiological and non-physiological effects (control group).

Main outcome variables
Primary recorded outcomes include systolic blood pressure, diastolic blood pressure, heart rate, oxygen saturation, child behavior, child's self-reported discomfort, treatment duration, pain after treatment and its duration, opposition to the next treatment session. and parental consent.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20110325006105N8**
Registration date: **2024-02-08, 1402/11/19**
Registration timing: **registered_while_recruiting**

Last update: **2024-02-08, 1402/11/19**
Update count: **0**

Registration date
2024-02-08, 1402/11/19

Registrant information

Name
Nahid Ramazani

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-01-21, 1402/11/01

Expected recruitment end date
2024-04-20, 1403/02/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of Physiologic and non physiologic Effects of Two Adjacent Primary Molars Treatment in One Single Session in5-7 years old children

Public title
Different Aspects of Two Adjacent Primary Molars Treatment

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Children aged 7-5 years without any physical or mental illnesses Cooperative based on the Frankl behavior rating scale (Frankl 3 or 4) Candidates for routine treatment for the first time (no previous treatment history) Having a minimum of four asymptomatic decayed primary molars requiring pulpotomy and SSC Requiring a minimum of three consecutive treatment sessions to treat all decayed teeth
Exclusion criteria:
Children with a history of unfavorable medical or dental conditions Tooth pain, except for food impaction Systemic illness or medication intake Any known allergies or contraindications to anesthesia drugs Non-cooperative children (Frankl 1) Deciduous teeth without succedaneous tooth buds

Age
From **5 years** old to **7 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **58**
More than 1 sample in each individual
Number of samples in each individual: **2**
two sides of dental arch

Randomization (investigator's opinion)
Randomized

Randomization description
Allocation of samples will be done using quadruple blocks, where half of the individuals are assigned to group one and the other half to group two. All possible quadruple scenarios are as follows: Where 'A' belongs to group one and 'B' belongs to group two. 1. A A B B 2. A B A B 3. A B B A 4. B B A A 5. B A B A 6. B A A B In the next step, each of these quadruple combinations will be assigned a number from 1 to 6. Following that, approximately 15 random quadruple blocks will be selected based on the total sample size and the sample size for each group. The order of these selected blocks will be determined, and the allocation of individuals to groups one and two will be based on these chosen orders. By continuing this process, we ensure that the difference between the two groups will not exceed two individuals at most.

Blinding (investigator's opinion)
Double blinded

Blinding description
The assessor of the physiological and non-physiological measures is currently blinded to which side (adjacent treatment of two decayed primary molars in one session under the experimental group and treatment of one decayed primary molar in one session under the control group) is being performed. The participant is unaware of how to check the sequence of sessions.

Placebo
Not used

Assignment
Crossover

Other design features
A split-mouth design is used to investigate the effect of treating two adjacent teeth on the variables. Two molars on the experimental side and one molar on the control side are treated. All children in the pediatric department are treated by two dental resident under the supervision of a pediatric specialist. For each participant, both sides of the jaw will be treated by a single operator in two separate consecutive sessions with a two-week interval between the treatment sessions. This time interval between sessions is planned to eliminate the effects of the first encounter on the outcomes of the second encounter. Additionally, to eliminate any unknown treatment effect from the first session to the second session, children will be randomly divided into two groups using a random block method. One group will receive single-tooth pulpotomy treatment and stainless steel crown (SSC) initially, while the other group will receive pulpotomy treatment for the adjacent molars and SSC in one session initially. Furthermore, depending on which dental arch (right or left) will receive the first treatment, two subgroups from each of the initial groups will be extracted using a random block method. For both sides, treatments are performed as a single session of complete treatment

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Zahedan University of Medical Sciences
Street address
Zahedan, Persian Gulf Blvd., College, resistance Research and Technology
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code

9816743463

Approval date

2023-12-27, 1402/10/06

Ethics committee reference number

IR.ZAUMS.REC.1402.379

Health conditions studied

1

Description of health condition studied

pulpotomy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Average systolic blood pressure. blood pressure, average diastolic blood pressure

Timepoint

in three separate times (time of completion of anesthesia administration, in the middle of the treatment and in the final moments of the treatment)

Method of measurement

"Systolic blood pressure" using "digital instrument with wrist cuff Diastolic blood pressure" using ""digital instrument with wrist cuff

2

Description

average heart rate

Timepoint

In three separate times (time of completion of anesthesia administration, in the middle of the treatment and in the final moments of the treatment)

Method of measurement

"heart rate" using "digital instrument with wrist cuff

3

Description

Average oxygen saturation

Timepoint

In three separate times (time of completion of anesthesia administration, in the middle of the treatment and in the final moments of the treatment)

Method of measurement

"oxygen saturation" using "pulse oximeter"

Secondary outcomes

1

Description

duration of treatment

Timepoint

The duration of the treatment is at the end of the treatment

Method of measurement

Treatment duration using cornometer

2

Description

the average number of consumed painkillers

Timepoint

The dose numbers of analgesic by asking the parents in the days after the treatment

Method of measurement

The dose numbers of analgesic by asking the parents in the days after the treatment

3

Description

the average behavior score

Timepoint

Average discomfort upon completion of treatment

Method of measurement

Frankle behavior rating scale

4

Description

the average discomfort level

Timepoint

Average discomfort upon completion of treatment

Method of measurement

Facial image score

5

Description

the average post-treatment pain

Timepoint

Average post-treatment pain as soon as the treatment is completed

Method of measurement

Wong baker faces pain

6

Description

the average parental satisfaction .

Timepoint

Parental consent upon completion of treatment

Method of measurement

parental satisfaction based on a five-point response

7

Description

next appointment refusal

Timepoint

apposition to meeting at the beginning of the second and third session

Method of measurement

refusal for the second and third session appointments based on the child's report.

Intervention groups

1

Description

Intervention side: Prior to injection, local gel will be used at the injection site. A volume of 1.8 milliliters of 2% lidocaine with 1/80000 epinephrine solution at room temperature will be slowly administered using a regular syringe (1 milliliter per minute, only one cartridge). For anesthesia of the upper and lower jaw, participants will receive infiltration and inferior alveolar nerve block sequentially using a 21-gauge needle with a 27-gauge and 35-gauge needle with a 27-gauge respectively. Intrapapillary anesthesia will be performed for complete anesthesia. After 15 minutes have elapsed since the administration of anesthesia, treatment will begin. All dental procedures will be performed using rubber dam isolation. After performing pulp treatment, the adjacent tooth will be restored using light-cured glass ionomer cement for crown restoration. Then, SSCs will be adjusted and cemented using glass ionomer cement

Category

Treatment - Surgery

2

Description

Control side: Intervention Group 1: Before injection, local gel will be used at the injection site. A volume of 1.8 milliliters of 2% lidocaine with 1/80000 epinephrine solution at room temperature will be slowly administered using a regular syringe (1 milliliter per minute, only one cartridge). For anesthesia of the upper and lower jaw, participants will receive infiltration and inferior alveolar nerve block sequentially using a 21-gauge needle with a 27-gauge and 35-gauge needle with a 27-gauge respectively. Intrapapillary anesthesia will be performed for complete anesthesia. After 15 minutes have elapsed since the administration of anesthesia, treatment will begin. All dental procedures will be performed using rubber dam isolation. After performing pulp treatment, a primary molar tooth will be restored using light-cured glass ionomer cement for crown restoration. Then, SSCs will be adjusted and cemented using glass ionomer cement

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Zahedan dental school

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Zahedan 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

Zahedan University of Medical Sciences

Full name of responsible person

Nahid Ramazani

Position

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)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is 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
Title and more details about the data/document
information about the main outcome and its comparison with different groups can be shared.
When the data will become available and for how long
Access period starts 6 months after the results are published.
To whom data/document is available
Researchers working in academic and scientific institutes, dental students, dentists.
Under which criteria data/document could be used
The ultimate goals are providing adequate dental services, creating a good experience, consolidating good communication between the individual child and dental team and avoiding any fear and anxiety throughout future life and improve treatment results. all dental researchers will be able to access the data.
From where data/document is obtainable
Dr.nahid ramazani ramazani77@gmail.com +989155009085
What processes are involved for a request to access data/document
please send an email to the respondent and state the resume and purpose of accessing the data for the respondent.The respondent will respond to the initial email within a week, and if documents need to be sent, the documents will be sent to the applicant within a month.
Comments