

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

The effect of administrating a sweet-tasting solution (30% Sucrose solution) in comparison to distilled water on pain perception caused by dental anesthesia injections in children aged of 6-10 years old: a randomized controlled trial

Protocol summary

Study aim

In this study, we intend to investigate the analgesic effects of sucrose before the injection of dental anesthesia in children.

Design

Clinical trial with control group, parallel groups, double-blind, randomized, phase 3 on 48 patients.

Settings and conduct

The location of the study will be the children's department of the Faculty of Dentistry, Tehran University of Medical Sciences. The study population will be 48 people who refer to the children's department, who are 6 to 10 years old and need the pulp treatment of the first deciduous molar. This study is double blind. The total number of children will be divided into two intervention and control groups using the block randomization method. The randomization unit will be individual. Numbers 1 to 48 will be placed in similar closed envelopes. Half are in the intervention group and the rest are in the control group. Randomization is done by a person who has no knowledge of the study protocol.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Children 6 to 10 years old; Having at least one mandibular primary molar that needs pulp therapy; Willingness and consent of parents to participate in the study. Non-inclusion criteria: dental emergencies such as traumatic dental injuries or tooth pain; Allergy to lidocaine or sucrose; previous anesthesia experience; abscess, redness and fistula at the injection site; systemic medical conditions (ASA class I or II); history of hospitalization; history of previous dental treatment; mental or anxiety disorders

Intervention groups

Before the injection for the intervention group, patients are asked to keep 20 ml of 30% sucrose solution in their mouth for 1 minute and then take it out. For the control

group, distilled water is prescribed instead of 30% sucrose solution.

Main outcome variables

Visual analogue scale grade ; sound, eye, body movement grade

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220917055974N1**

Registration date: **2022-10-28, 1401/08/06**

Registration timing: **retrospective**

Last update: **2022-10-28, 1401/08/06**

Update count: **0**

Registration date

2022-10-28, 1401/08/06

Registrant information

Name

Elahe Darvishi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 6621 2744

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elahedarvishi467@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-29, 1401/07/07

Expected recruitment end date

2022-10-06, 1401/07/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of administrating a sweet-tasting solution (30% Sucrose solution) in comparison to distilled water on pain perception caused by dental anesthesia injections in children aged of 6-10 years old: a randomized controlled trial

Public title

The effect of using sweet-tasting solutions on pain perception caused by dental anesthesia injections in children

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Children 6 to 10 years old Having at least one mandibular primary molar that needs pulp therapy Willingness and permission of parents to participate in the study

Exclusion criteria:

Dental emergencies such as traumatic dental injuries or tooth pain Non-cooperation of children Allergy to lidocaine or sweet substances such as sucrose Existence of previous anesthesia experience Presence of abscess, redness, and fistula at the injection site Presence of systemic medical conditions (ASA class I or II) History of hospitalization History of previous dental treatment History of mental or anxiety disorders

Age

From **6 years** old to **10 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **48**

Randomization (investigator's opinion)

Randomized

Randomization description

The total number of children will randomly be divided into two groups of 24 people, case and control, using the block randomization method. The randomization unit will be individual. Numbers 1 to 48 will be written on similar papers and will be placed in similar closed envelopes. Half of these envelopes are placed in the intervention group and the other half in the control group. Randomization will done by a person who has no

familiarity with the study protocol. Similar laboratory containers will be labeled with numbers 1 to 48. According to the numbers in the control and intervention groups, laboratory containers are filled with sucrose solution or distilled water. The person who fills the laboratory containers has no knowledge of the study process.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participation in this study will be with the full consent of the parents of the patients, but the patient or his parents will not know that they are in the control or intervention group. A person who divides the numbers 1 to 48 into two groups will not know about the study protocol. Next, the person who fills the laboratory containers with sucrose solution in the intervention group and distilled water in the control group is not familiar with the study. A dentist who administers anesthetic injections to children and observes and records the child's behavior related to pain does not know the type of solution used by the child.

Placebo

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

No. 54 , Kohansal alley., South Sajjad Blvd., Tehran

City

Tehran

Province

Tehran

Postal code

1369993495

Approval date

2022-04-26, 1401/02/06

Ethics committee reference number

IR.TUMS.DENTISTRY.REC.1401.014

Health conditions studied**1****Description of health condition studied**

Dental caries with pulp exposure

ICD-10 code

K02

ICD-10 code description

Primary outcomes

1

Description

Visual analogue scale grade

Timepoint

Visual analog scale score measurement immediately after the intervention

Method of measurement

Visual analog scale: a spectrum with 10 numbers and schematic images next to the numbers, in which the patient expresses the amount of pain caused by the injection that he has experienced with the help of these numbers, and the greater the pain, the closer the number will be to 10.

2

Description

sound, eye, body movement grade

Timepoint

Measure the score of sound, eye, body movement, immediately after the intervention

Method of measurement

sound, eye, body movement grade: a pain measurement tool that measures pain intensity based on three characteristics of sound, eye movements and body movement. The amount of pain shows a number between 0 and 9, which we consider 3 points for each characteristic.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Sucrose solution 30%, chemical formula C₁₂H₂₂O₁₁, produced by Millipore Sigma, in the amount of 20 ml, is kept in the mouth for one minute before injection and then is emitted.

Category

Prevention

2

Description

Control group: Distilled water, with the chemical formula H₂O, produced by the 3 Sib Teb company, in the amount of 20 ml before injection, is kept in the mouth for one minute and then is emitted out.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Faculty of Dentistry, Tehran University of Medical Sciences

Full name of responsible person

Elahe Darvishi

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North Kargar Blvd., Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Tabassom Houshmand

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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

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
Elahe Darvishi
Position
student
Latest degree
A Level or less
Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

The data file of the participants will be subjected to statistical analysis and the results will be published in the form of an article. The data file of the participants will not contain more useful information and includes personal information.

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Not applicable

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

Not applicable

Title and more details about the data/document

The study protocol, informed consent and clinical study report will be published in the relevant proposal, the thesis text and the article that will be written in the end.

When the data will become available and for how long

Once the proposal is approved by the ethics committee, it is possible to access the text of the proposal and the clinical study report, as well as the text of the consent form.

To whom data/document is available

People who have permission to access the website of the library of Tehran University of Medical Sciences, Faculty of Dentistry, will eventually have access to the text of the desired thesis and also the article resulting from this study will be published in reputable scientific journals and the general public will have the opportunity to access the article.

Under which criteria data/document could be used

The data can be used for the thesis of the general dentistry degree and also the resulting article.

From where data/document is obtainable

Tehran University of Medical Sciences Faculty of
Dentistry Library Address: North Kargar Street, Tehran
<https://dentistry.tums.ac.ir/fa/library>

What processes are involved for a request to access

data/document

Theses can be accessed in full text through the
university library portal at <http://lib.tums.ac.ir>.

Comments