Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 May 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)

Phone
+98 21 6621 2744

Email address
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

Dental caries

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
Street address
North Kargar Blvd., Tehran
City
Tehran
Province
Tehran
Postal code
۱۴۳۹۹۵۵۹۹۱
Phone
+98 21 8835 1258
Email
dentistry@tums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Tabassom Houshmand
Street address
North Kargar Blvd, Tehran
City
Tehran
Province
Tehran
Postal code
۱۴۳۹۹۵۵۹۹۱
Phone
+98 21 8835 1258
Email
dentistry@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
Elahe Darvishi
Position
student
Latest degree
A Level or less
Other areas of specialty/work
Dentistry
Street address
South Sajjad blvd
City
Tehran
Province
Tehran
Postal code
1369993494
Phone
+98 21 6621 2744
Email
elahedarvishi467@yahoo.com

Person responsible for scientific 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
Dentistry
Street address
South Sajjad Blvd., Tehran
City
Tehran
Province
Tehran
Postal code
1369993495
Phone
+98 21 6621 2744
Email
elahedarvishi467@yahoo.com

Person responsible for updating data

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
Dentistry
Street address
South Sajjad Blvd., Tehran
City
Tehran
Province
Tehran
Postal code
1369993495
Phone
+98 21 6621 2744
Email
elahedarvishi467@yahoo.com

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