Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Effect of injection site precooling versus benzocaine gel on pain perception during infiltration local anesthesia of anterior teeth in children: a randomized clinical trial

Protocol summary

Study aim
To assess the effect of injection site precooling versus benzocaine gel on pain perception during infiltration local anesthesia of anterior teeth in children

Design
This is a randomized clinical trial with control group, phase III, in which eligible patients will be randomly assigned through the block randomization to the intervention and control groups

Settings and conduct
This study will be performed in the School of Dentistry in Hamadan city on 52 children who need infiltration local anesthesia of anterior teeth. The patients will be randomly assigned to the intervention and control groups through the block randomization. Blinding is not possible in this study.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age 8 to 10 years; Indication of local anesthetic injection for anterior teeth; Exclusion criteria: Presence of abscess and fistula in the injection site; Systemic diseases or mental disorders

Intervention groups
Intervention group: Put ice on the injection site for one minute Control group: Apply benzocaine gel to the injection site for one minute

Main outcome variables
Primary outcome: Intensity of pain on the injection site, behavior of the child

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120215009014N418**
Registration date: **2022-03-08, 1400/12/17**
Registration timing: **prospective**
Last update: **2022-03-08, 1400/12/17**
Update count: **0**

Registration date
2022-03-08, 1400/12/17

Registrant information

Name
Jalal Poorolajal

Name of organization / entity
Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-04-04, 1401/01/15

Expected recruitment end date
2022-06-21, 1401/03/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of injection site precooling versus benzocaine gel on pain perception during infiltration local anesthesia of anterior teeth in children: a randomized clinical trial

Public title
Effect of injection site precooling versus benzocaine gel

on pain perception during infiltration local anesthesia of anterior teeth in children

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 8 to 10 years; Indication of local anesthetic injection for anterior teeth;

Exclusion criteria:

Presence of abscess and fistula in the injection site; Systemic diseases or mental disorders

Age

From **8 years** old to **10 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **52**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients will be randomly assigned to intervention and control groups using block randomization. For this purpose, we will prepare two envelopes, writing in one envelopes the name of the intervention and in another the name of the control. The envelopes will be randomly drawn one at a time for each patient without replacement. This action repeated until the sample size is reached.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Approval date

2021-10-18, 1400/07/26

Ethics committee reference number

IR.UMSHA.REC.1400.556

Health conditions studied

1

Description of health condition studied

Pain

ICD-10 code

G89

ICD-10 code description

Pain, not elsewhere classified

Primary outcomes

1

Description

Primary outcome: Intensity of pain on the injection site pain

Timepoint

Immediately after injection

Method of measurement

Using Visual Analogue Scale (VAS)

2

Description

Behavior of the child

Timepoint

Immediately after injection

Method of measurement

Using the Sound, Eye, Motion Scale (SEM) scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Put ice on the injection site for one minute

Category

Treatment - Other

2

Description

Control group: Apply benzocaine gel to the injection site for one minute

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
School of Dentistry in Hamadan city

Full name of responsible person
Zamanian Mohammad Amin

Street address
School of Dentistry, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Hamedan University of Medical Sciences

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
Hamedan 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
Hamedan University of Medical Sciences

Full name of responsible person
Zamanian Mohammad Amin

Position
Dentistry Student

Latest degree
Medical doctor

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