

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 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

Country

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.

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Reza Shokoohi

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Hamadan University of Medical Sciences, Shahid Fahmideh Ave

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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 scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Dr. Mahdi Saharkhizan

Position

Pediatric Dentist

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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Person responsible for updating data

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Jalal Poorolajal

Position

Professor of Epidemiology

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

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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