Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

A randomized clinical trial study of the effect of lavender and clove herbal topical anesthetics compared to benzocaine on dental injection pain in children

Protocol summary

Study aim

Many researchers have studied the effect of using topical anesthetic agents at the injection site for pain relief; however, non pharmacological methods are still under investigation, and there remains an unexplored and emerging research area with very limited studies. Since no study has compared these two substances, this study is designed and conducted to compare the effect of topical herbal anesthesia of lavender and clove on the level of pain during dental injection in children.

Design

A crossover study involving at least 24 children requires three sessions of maxillary posterior infiltration anesthesia. Randomization is performed using blocks of six, with triple blinding. Three topical anesthetics—20% benzocaine, 100% lavender gel, and 100% clove gel—are applied for 2 minutes prior to injection of 2% lidocaine with epinephrine. Pain intensity during injection is assessed using the FLACC scale, and post-injection pain is measured using the FPS-R scale.

Settings and conduct

School of Dentistry, Tehran University of Medical Sciences

Participants/Inclusion and exclusion criteria

Inclusion: Healthy children (ASA I–II), cooperative behavior (Frankl 3 or 4), no recent medication (past 12h), requiring three maxillary infiltration sessions, with verbal communication ability. Exclusion: Systemic disease, anxiety/phobia, active infection, injection site pathology, behavioral/learning disorders, prior dental treatment, or allergy history.

Intervention groups

Topical anesthesia prior to injection is performed using: 1. 20% benzocaine topical anesthetic, 2. 100% lavender topical gel, 3. 100% clove topical gel.

Main outcome variables

FPS-R-based comparison of topical anesthesia effects in clove, lavender, and control (benzocaine) groups. - FLACC-based comparison of topical anesthesia effects in clove, lavender, and control (benzocaine) groups.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250811066815N1**
Registration date: **2025-08-13, 1404/05/22**
Registration timing: **prospective**

Last update: **2025-08-13, 1404/05/22**
Update count: **0**

Registration date

2025-08-13, 1404/05/22

Registrant information

Name

Haniyeh Alavi Milani

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-09-06, 1404/06/15

Expected recruitment end date

2025-10-22, 1404/07/30

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
A randomized clinical trial study of the effect of lavender and clove herbal topical anesthetics compared to benzocaine on dental injection pain in children

Public title
The effect of lavender and clove herbal topical anesthetics compared to benzocaine on dental injection pain in children
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
ASA physical status classification I and II according to the American Society of Anesthesiologists (ASA). Frankl behavioral rating score of 3 (positive) or 4 (definitely positive). No use of analgesics or sedatives in the past 12 hours. All patients require 3 treatment sessions by infiltration injection of posterior maxillary teeth. All patients have the ability to establish appropriate verbal communication.
Exclusion criteria:
Have systemic disease. Have anxiety disorder and phobia. Have abscess or fascial space infection. Presence of any pathology in the injection area. Children with behavioral and learning disorders. Children with a history of dental treatment. Children with a history of allergy (food, plants, etc.).
Age
From **6 years** old to **8 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **24**
More than 1 sample in each individual
Number of samples in each individual: **3**
Benzocaine topical gel, Lavender essential oil, Clove essential oil
Randomization (investigator's opinion)
Randomized
Randomization description
Given the six possible sequential models for the interventions, randomization of the samples is performed using blocks of six and with the aid of Excel software. The randomization process is conducted by the study's methodology consultant, and the other researchers are blinded to the allocation sequence. Once the intervention order is determined, the allocation for each patient is placed sequentially in sealed, numbered envelopes. During the intervention phase, these envelopes are opened in order, and the interventions are carried out accordingly.
Blinding (investigator's opinion)
Triple blinded
Blinding description
Blinding in the study is implemented through three methods: 1) The three topical gels are made to appear identical, 2) The operator is unaware of the order in which the gels are applied, 3) The evaluator is unaware of the order in which the gels are applied.
Placebo
Not 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. 36, Shahin Ave., Sattarkhan Ave,.
City
Tehran
Province
Tehran
Postal code
۴۵۶۹۱۶۸۳۱
Approval date
2025-04-28, 1404/02/08
Ethics committee reference number
IR.TUMS.DENTISTRY.REC.1404.015

Health conditions studied

1

Description of health condition studied
Topical anesthesia with lavender, clove, and benzocaine
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
The amount of pain of anesthetic local injection
Timepoint
Post-anesthetic injection
Method of measurement
Face, Legs, Activity, Cry, Consolability

2

Description
The amount of pain of anesthetic local injection
Timepoint
Post-anesthetic injection
Method of measurement
Faces Pain Scale-Revised

Secondary outcomes

1

Description
aste of the topical anesthetic gel
Timepoint
Post anesthesia injection
Method of measurement
Child’s selection from good, average, and bad

Intervention groups

1

Description
Intervention group: Lavender essential oil
Category
Treatment - Drugs

2

Description
Intervention group: Clove essential oil
Category
Treatment - Drugs

3

Description
Control group: Topical benzocaine gel
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Pediatric Department of Tehran Dental School
Full name of responsible person
Haniyeh alavi milani
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End of North Karegar Street, Next to the Atomic Energy Organization, Before the Hakim Expressway East Exit, School of Dentistry, Tehran University of Medical Sciences Tehran, Iran
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Sponsors / Funding sources

1

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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
Persons

Person responsible for general inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Haniyeh Alavi Milani
Position
Pediatric Dentistry Resident
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)
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
Yes - There is a plan to make this available
Data Dictionary
Not applicable
Title and more details about the data/document
All data may be shared, provided that individuals have been properly de-identified.
When the data will become available and for how long
Access to the data will commence two months following the publication of the results.
To whom data/document is available
Researchers working at academic and research institutions
Under which criteria data/document could be used
Data may be used for future research in dental science without restriction
From where data/document is obtainable
Alavi137516.ha@gmail.com
What processes are involved for a request to access data/document
The requester must submit their application via the platform or email. After initial review and approval, a confidentiality agreement will be sent. Once the signed form is received, the data will be prepared and delivered. Estimated time to receive the files: 2 to 4 weeks, depending on data volume and number of requests.
Comments