

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

The effect of acupressure at the LI4 point on injection pain of local anesthesia in children

Protocol summary

Study aim

Determining the effect of acupressure at the LI4 point on injection pain of local anesthesia in children

Design

Sham controlled clinical trial, cross over, double-blinded, coin flip randomization, on 23 samples.

Settings and conduct

During the study, children who refer to the pediatric department of the School of Dentistry of Tehran University of Medical Sciences for treatment will be included in the study if they are eligible. It will be randomly determined with the use of a coin that the first session is acupressure or sham. This study will be double-blind so that the children and their parents and the person recording the pain intensity will not know about the type of intervention.

Participants/Inclusion and exclusion criteria

The samples are among children aged 6-12 years who have grade 1 or 2 according to the criteria of the American Society of Anesthesiology, have a score of 3 (positive) or 4 (completely positive) according to Frankel's behavioral criteria, and need a nerve block or supra periosteal injection (and the type of injection in two sessions is the same). If there is a restriction such as a wound or a bruise at the desired acupoint or there is a local or systemic infection, it will not be included in the study.

Intervention groups

Each participant is treated with the same anesthesia injection technique in at least two sessions, and the studied interventions are performed before the injection. In the intervention session, finger pressure is applied to the LI4 acupoint, and in the control session (placebo) as a sham, the LI4 point is only touched.

Main outcome variables

The pain of local anesthesia injection using face, legs, activity, cry, consolability scale and Faces Pain Scale-Revised

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230502058053N1**

Registration date: **2023-06-27, 1402/04/06**

Registration timing: **prospective**

Last update: **2023-06-27, 1402/04/06**

Update count: **0**

Registration date

2023-06-27, 1402/04/06

Registrant information

Name

Hanieh Moghimi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-23, 1402/06/01

Expected recruitment end date

2023-12-21, 1402/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of acupressure at the LI4 point on injection pain of local anesthesia in children	
Public title	
Effect of acupressure on injection pain of local anesthesia	
Purpose	
Treatment	
Inclusion/Exclusion criteria	
Inclusion criteria:	
Children with an American Society of Anesthesiologists physical status of I or II Children with a Frankl behavior scale of 3 (positive) or 4 (definitely positive) Not receiving analgesics or sedatives at least 12 hours before the procedure Needing nerve block or supra periosteal injection (same injection technique for 2 sessions)	
Exclusion criteria:	
Be familiar with acupressure techniques Limitation on the acupoint like ulcers or bruise Needing for needle re-entry during injection Local or systemic infection	
Age	
From 6 years old to 12 years old	
Gender	
Both	
Phase	
N/A	
Groups that have been masked	
- Participant - Outcome assessor	
Sample size	
Target sample size: 23	
More than 1 sample in each individual	
Number of samples in each individual: 2	
In each patient, pain during injection for two teeth that are similar in terms of injection technique will be recorded in two different sessions, each based on acupressure intervention or sham (as a placebo control).	
Randomization (investigator's opinion)	
Randomized	
Randomization description	
With a coin flip randomization, each participant allocates to intervention or control (placebo) in the first session.	
Blinding (investigator's opinion)	
Double blinded	
Blinding description	
Participants and outcome evaluators are not familiar with acupressure techniques. And all the steps in the control (placebo) and intervention sessions are as same as each other, but in the control (placebo) session, LI4 acupoint will be touched.	
Placebo	
Used	
Assignment	
Crossover	
Other design features	
Secondary Ids	
empty	
Ethics committees	
<u>1</u>	
Ethics committee	
Name of ethics committee	
Ethics committee of school of dentistry of Tehran University of Medical Sciences	
Street address	
School of dentistry of Tehran University of Medical Sciences, next to Atomic Energy Organization, North Karegar St.	
City	
Tehran	
Province	
Tehran	
Postal code	
۱۳۳۹۹۵۵۹۹۱	
Approval date	
2023-05-22, 1402/03/01	
Ethics committee reference number	
IR.TUMS.DENTISTRY.REC.1402.016	
Health conditions studied	
<u>1</u>	
Description of health condition studied	
The pain of local anesthesia injection	
ICD-10 code	
ICD-10 code description	
Primary outcomes	
<u>1</u>	
Description	
Pain of dental injection	
Timepoint	
During injection and 5 minutes after injection	
Method of measurement	
1)face, legs, activity, cry, consolability scale 2) faces pain scale-revised	
Secondary outcomes	
empty	
Intervention groups	
<u>1</u>	
Description	
With the flip of a coin, it is determined that each participant will receive the acupressure intervention or the control in the first session. So, if the acupressure intervention is performed in the first session, the control intervention will be performed in the second session and vice versa. Intervention session: Acupressure is performed by only one trained person. The acupoint LI4 (He Gu) is identified on the back surface of the hand and halfway between the first and second metacarpal bones	

(a little closer to the second metacarpal). Acupoint stimulation is done by pressing the thumb for 2 seconds and ten times. Then pressure is continuously applied for 10 seconds. And finally, the pressure is applied again for 2 seconds and ten times. The same procedure is repeated for the opposite hand. After that, the required dental injection is performed. Injection with 2% lidocaine; epinephrine 1.80000 is done in the maximum amount of 1.8 cc and one person does all the injections.

Category

Treatment - Other

2**Description**

Control session (placebo): In this session as a sham, all the process mentioned in the previous section will be done, with the difference that the LI4 point is only touched by considering the mentioned times.

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

School of dentistry, Tehran University of Medical Sciences

Full name of responsible person

Mahdie sadat Moosavi

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School of dentistry of Tehran University of Medical Sciences, next to Atomic Energy Organization, North Karegar St

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Akbar Fotoohi

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Research and Technology Vice-Chancellor, 6th floor, Central Organization of the Tehran University of Medical Sciences, corner of Qods St., Keshavarz Blvd.

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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

Hanieh Moghimi

Position

postgraduate 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**

Tehran University of Medical Sciences

Full name of responsible person

Hanieh Moghimi

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Latest degree

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Person responsible for updating data

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Position

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Latest degree

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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

Patients confidentiality

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

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

Not applicable

Data Dictionary

Not applicable