

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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Email address

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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		Ethics committees	
Public title	Effect of acupressure on injection pain of local anesthesia	<u>1</u>	
Purpose	Treatment	Ethics committee	
Inclusion/Exclusion criteria		Name of ethics committee	Ethics committee of school of dentistry of Tehran University of Medical Sciences
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)	Street address	School of dentistry of Tehran University of Medical Sciences, next to Atomic Energy Organization, North Karegar St.
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	City	Tehran
Age	From 6 years old to 12 years old	Province	Tehran
Gender	Both	Postal code	۱۳۳۹۹۵۵۹۹۱
Phase	N/A	Approval date	2023-05-22, 1402/03/01
Groups that have been masked	- Participant - Outcome assessor	Ethics committee reference number	IR.TUMS.DENTISTRY.REC.1402.016
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).	Health conditions studied	
Randomization (investigator's opinion)	Randomized	<u>1</u>	
Randomization description	With a coin flip randomization, each participant allocates to intervention or control (placebo) in the first session.	Description of health condition studied	The pain of local anesthesia injection
Blinding (investigator's opinion)	Double blinded	ICD-10 code	
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.	ICD-10 code description	
Placebo	Used	Primary outcomes	
Assignment	Crossover	<u>1</u>	
Other design features		Description	Pain of dental injection
Secondary Ids	empty	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

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

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Phone

+98 21 4279 4025

Email

dentistry@tums.ac.ir

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

Tehran University of Medical Sciences

Full name of responsible person

Akbar Fotoohi

Street address

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

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

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Person responsible for updating data

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Full name of responsible person

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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