# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 Nov 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**

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Iran (Islamic Republic of)

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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

**1**

**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.
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**Postal code**
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**Approval date**
2023-05-22, 1402/03/01
**Ethics committee reference number**
IR.TUMS.DENTISTRY.REC.1402.016

## Health conditions studied

**1**

**Description of health condition studied**
The pain of local anesthesia injection
**ICD-10 code**
**ICD-10 code description**

## Primary outcomes

**1**

**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

**1**

**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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## 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**

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**Position**

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**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)**
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