

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Evaluating the effectiveness of acupressure in controlling the anxiety of children with dental caries during inferior alveolar nerve block

Protocol summary

Study aim

Evaluation of the effect of acupressure in controlling the anxiety of patients before and after inferior alveolar nerve block.

Design

A two-group clinical trial with a control group with randomized parallel groups without blinding is conducted on 75 patients aged 6 to 10 years. Sealed envelopes are used for randomization, including three groups with codes 1, 2 and 3. After opening the envelope, the intervention related to that code is applied to the desired patient.

Settings and conduct

Place of conducting the study: pediatric department of Faculty of Dentistry, Mashhad University of Medical Sciences; Population: Children aged 6-10 years with dental caries; There is no blinding in this study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Aged 6 to 10 years; need for dental treatment; Patients who have no history of receiving inferior alveolar nerve block. Exclusion criteria: The use of anti-anxiety drugs; emergency patients; patients who receive medication for any chronic disease; patients with chronic systemic disease; patients who have an anxiety disorder or depression; patients who have used acupuncture or acupressure in the last 6 months.

Intervention groups

Intervention group 1: the group that is ready to be treated using acupressure on the tai yang point.
Intervention group 2: the group that is ready to be treated using acupressure on the sham point. Control group: receiving usual treatments without receiving acupressure.

Main outcome variables

Anxiety score based on Venham scale, heart rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170204032380N2**

Registration date: **2023-12-17, 1402/09/26**

Registration timing: **prospective**

Last update: **2023-12-17, 1402/09/26**

Update count: **0**

Registration date

2023-12-17, 1402/09/26

Registrant information

Name

Maryam Mehrabkhani

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 51 3882 9501

Email address

mehrabkhanim@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-22, 1402/10/01

Expected recruitment end date

2024-06-04, 1403/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effectiveness of acupressure in controlling the anxiety of children with dental caries during inferior

alveolar nerve block	
Public title	The effect of acupressure on anxiety
Purpose	Other
Inclusion/Exclusion criteria	
Inclusion criteria:	Being at the age of 6-10 years old Need for inferior alveolar nerve block for dental treatment No history of receiving inferior alveolar nerve block
Exclusion criteria:	Use of anti-anxiety drugs Use of psychiatric drugs Emergency patients Patients who receive medicine for any chronic disease Chronic systemic disease Patients who have anxiety disorder or depression Patients who have used acupuncture or acupressure in the last 6 months
Age	From 6 years old to 10 years old
Gender	Both
Phase	N/A
Groups that have been masked	No information
Sample size	Target sample size: 75
Randomization (investigator's opinion)	Randomized
Randomization description	The method of randomization through the preparation of sealed envelopes includes three groups corresponding to codes 1, 2 and 3. The envelope selection for each patient is done randomly and after opening the intervention envelope, the corresponding code is applied to the desired patient
Blinding (investigator's opinion)	Not blinded
Blinding description	
Placebo	Not used
Assignment	Parallel
Other design features	
Secondary Ids	empty
Ethics committees	
<u>1</u>	
Ethics committee	
Name of ethics committee	Research Ethics Committees of School of Dentistry - Mashhad University of Medical Sciences
Street address	Faculty of dentistry- Mashhad university of Medical Sciences - Vakilabad Blvd.
City	

Mashhad	
Province	Razavi Khorasan
Postal code	9177948959
Approval date	2023-10-22, 1402/07/30
Ethics committee reference number	IR.MUMS.DENTISTRY.REC.1402.061
Health conditions studied	
<u>1</u>	
Description of health condition studied	Anxiety
ICD-10 code	F41.1
ICD-10 code description	Generalized anxiety disorder
Primary outcomes	
<u>1</u>	
Description	Anxiety score based on the Venham Clinical Anxiety Scale
Timepoint	Before injection of local anesthesia And After injection of local anesthesia
Method of measurement	Venham Clinical Anxiety Rating Scale
Secondary outcomes	
<u>1</u>	
Description	Heart rate
Timepoint	Before injection of local anesthesia And After injection of local anesthesia
Method of measurement	pulse oximeter
Intervention groups	
<u>1</u>	
Description	Intervention group 1: The group that is ready to be treated using acupressure on the tai yang point, this point is located between the two eyebrows (glabella) and can control anxiety. The method of acupressure is using the index finger between the patient's eyebrows, a circular pressure movement is applied for one minute, and then the anesthetic is injected.
Category	Behavior

2

Description

Intervention group 2: This group is ready to be treated using acupuncture on the sham point. The Sham point is located in the middle of the mentolabial fold and has no anxiety control properties at all. This point is easy to find and it is in the same area of the face and near the Tai Yang point, and patients do not feel much difference when they communicate with each other procedure is the same as the first intervention group, and applying rotational pressure on the mento-labial fold

Category

Behavior

3

Description

Control group: Children prepared for dental treatment in the usual way (without applying acupuncture). In this group, the usual method of local anesthesia injection is performed in such a way that after determining the patient's anxiety level and application of topical anesthesia, injection of anesthetic solution is performed.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Dental school of Mashhad University of Medical Sciences

Full name of responsible person

Maryam Mehrabkhani

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Vakilabad Blvd.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

Street address

Research and Technology Vice-Chancellor, Qurashi Building, Next to Hoveizeh cinema, Daneshgah Street

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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

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Maryam Mehrabkhani

Position

Associate professore

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Faculty of Dentistry; Mashhad University of Medical Sciences Campus; Vakil Abad Blvd.

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Person responsible for scientific inquiries

Contact

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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

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