

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

The Effect of Acupressure on Anxiety and Pain of Local Anesthesia Injection in 5-7 Years Children

Protocol summary

Study aim

Determination of the Effect of Acupressure on Anxiety and Pain of Local Anesthesia Injection in 5-7 Years Children

Design

2 randomized selected groups with 30 person that evaluated in the form of parallel and blinded.

Settings and conduct

This research is a blinded clinical trial that performed in children aged 5-7 years old who need to dental treatments. Children are divided into two groups of thirty and level of anxiety and pain are measured before and after acupressure. Participants and dentist and analyst will be blinded.

Participants/Inclusion and exclusion criteria

the children in the age of 5-7 years old that have two carious primary molars in mandible or maxilla that required treatment with local anesthesia there were any wound or scars in acupressure points history of systemic disease mental retardation history of unfavorable dentistry experiment or hospitalization history of severe dental pain & acute dental infection Lack of cooperation

Intervention groups

Intervention group: Children who receive acupressure at the main point Control group: Children who receive acupressure at the placebo point.

Main outcome variables

anxiety and pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171020036896N6**

Registration date: **2018-05-30, 1397/03/09**

Registration timing: **registered_while_recruiting**

Last update: **2018-05-30, 1397/03/09**

Update count: **0**

Registration date

2018-05-30, 1397/03/09

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 32119023

Email address

sajadi@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-22, 1397/03/01

Expected recruitment end date

2018-09-22, 1397/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Acupressure on Anxiety and Pain of Local Anesthesia Injection in 5-7 Years Children

Public title

The Effect of Acupressure on Anxiety and Pain of Local Anesthesia Injection

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

the children in the age of 5-7 years old that have two

carious primary molars in mandible or maxilla that required treatment with local anesthesia there were any wound or scars in acupressure points Exclusion criteria: history of systemic disease mental retardation history of unfavorable dentistry experiment or hospitalization history of severe dental pain & acute dental infection Lack of cooperation Age From 5 years old to 7 years old Gender Both Phase N/A Groups that have been masked • Participant • Investigator • Data analyser Sample size Target sample size: 60 More than 1 sample in each individual Number of samples in each individual: 2 In each participant, two interventions take place within two weeks, once acupressure at the main point and once at the point of the placebo, and its effect is measured on anxiety and pain Randomization (investigator's opinion) Randomized Randomization description Simple randomization or unrestricted method will be used and randomization unit is Individual .we will use from Flip the coin from the methods of simple randomization because there are 2 groups in this study that actually the tool of randomization is coin. As one of the study groups, I consider the heads and the other group as tails, and according to the size of the sample(60 person), the coin is toss-up. So the subjects are divided into two groups (anxiety and pain groups). The next step Allocation concealment will be done, In such a way that the allocated group is not known before the assignment of the individual. To achieve this goal, a non-transparent, sealed, random sequence envelope is used . In this way, the statistical specialist will provide 60 envelopes and each of the randomly generated links will be recorded on a card and the cards are arranged in the envelopes . In order to maintain a random sequence, the numbering of envelopes on the outer surface is done in the same order. Finally, the envelopes are enclosed and placed in the box, respectively. At the time of the implementation of the study, according to the order of entry of eligible participants, one of the envelopes is opened respectively and will determine the group assigned to that participant. In this study, the assistant of Pediatric Dentistry examines the participants in terms of inclusion and exclusion criteria. Randomization methods are done by a statistical specialist and performance of the study is done by a trained assistant of Pediatric Dentistry. Blinding (investigator's opinion) Triple blinded Blinding description	Participants do not know the type of intervention (the main point of acupressure) A researcher who performs local anesthesia is not aware of the type of intervention The data analyzer is also unaware of the groups. Placebo Used Assignment Parallel Other design features Secondary Ids empty Ethics committees 1 Ethics committee Name of ethics committee The Ethic Committee of Kerman University of Medical Sciencess Street address Vice-Chancellor for Research, Kerman University of Medical Sciences, Tahmasbabad cross, Jahad Street,Kerman City Kerman Province Kerman Postal code 7619813159 Approval date 2018-05-29, 1397/03/08 Ethics committee reference number IR.KMU.REC.1397.067 Health conditions studied 1 Description of health condition studied anxiety and pain ICD-10 code V ICD-10 code description Mental and behavioural disorders Primary outcomes 1 Description the level of anxiety Timepoint before and after performance of acupressure Method of measurement visual analogue scale 2 Description
---	---

the level of pain
Timepoint
before and after performance of acupressure
Method of measurement
visual analogue scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: The application of acupressure in the main point of reduction anxiety

Category

Rehabilitation

2

Description

Intervention group 2: The application of acupressure in the main point of reduction pain

Category

Rehabilitation

3

Description

Control group 1: The application of acupressure in the placebo point of reduction anxiety

Category

Rehabilitation

4

Description

Control group 2: The application of acupressure in the placebo point of reduction pain

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Pediatric Department of Dental School of Kerman
University of Medical Sciences

Full name of responsible person

Fatemeh Sadat Sajadi

Street address

Pediatric Department, School of Dentistry, Shafa
Street

City

Kerman

Province

Kerman

Postal code

7618759689

Phone

+98 34 3211 9021

Email

Sajadi@kmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Dr Abbas Pardakhti

Street address

No.1 Ave, Tahmasebabad Intersection, Research - Vice
Chancellor of Kerman University of Medical Science

City

Kerman

Province

Kerman

Postal code

7619813159

Phone

+98 34 3226 3815

Email

kmu_research@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Kerman University of Medical Sciences

Proportion provided by this source

60

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

Kerman University of Medical Sciences

Full name of responsible person

Dr Hamidreza Poureslami

Position

Professor of Pediatric Department, Faculty of
Dentistry ,

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Pediatric Department, School of Dentistry, Shafa

Street, Kerman

City

Kerman

Province

Kerman

Postal code

7618759689

Phone

+34 32119021

Email

poureslami@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Fatemeh Sadat Sajadi

Position

Associate Professor of Pediatric Dentistry

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Pediatric Department, School of Dentistry, Shafa Street, Kerman

City

Kerman

Province

Kerman

Postal code

7618759689

Phone

+34 32119021

Email

sajadi@kmu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Fatemeh Sadat Sajadi

Position

Associate Professor of Pediatric Dentistry

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Pediatric Department, School of Dentistry, Shafa Street, Kerman

City

Kerman

Province

Kerman

Postal code

7618759689

Phone

+34 32119021

Email

sajadi@kmu.ac.ir

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

Because the study data do not have any other application.

Study Protocol

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

Statistical Analysis Plan

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

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

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

Data Dictionary

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