

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

Effect of acupressure versus control group on anxiety in 8-12 years patients with molar teeth caries: a randomized clinical trial

Protocol summary

Study aim

To determine the effect of acupressure versus control group on anxiety in 8-12 years patients with molar teeth caries

Design

This is a randomized clinical trial, phase II, in which 60 eligible patients will be randomly assigned to the intervention and control groups

Settings and conduct

The eligible children with molar teeth caries referring to the School of Dentistry in Hamadan city during the study period will be enrolled in the trial and will be randomly assigned to the intervention and control groups through the drawing of lots.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 8 to 12 years, Class 1 caries penetrates into the dentin of deciduous molars, Frankel Behavioral Index Grade 2 to 3, No previous history of dental treatment Exclusion criteria: Coagulation disorder, Severe dental caries, Pulp tooth involvement, Mental or cognitive disorder

Intervention groups

Intervention group 1: Using acupressure bracelet with push-button at point P6 five minutes before repairing tooth decay up to one minute after work Intervention group 2: Using conventional bracelet without push-button at point P6 five minutes before repairing tooth decay up to one minute after work Control group: Repairing tooth decay without using a bracelet

Main outcome variables

Primary outcome: The mean score of anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N371**

Registration date: **2020-11-11, 1399/08/21**

Registration timing: **prospective**

Last update: **2020-11-11, 1399/08/21**

Update count: **0**

Registration date

2020-11-11, 1399/08/21

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 81 1838 0090

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-11-21, 1399/09/01

Expected recruitment end date

2021-02-19, 1399/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of acupressure versus control group on anxiety in 8-12 years patients with molar teeth caries: a randomized clinical trial

Public title

Effect of acupressure versus control group on anxiety in 8-12 years patients with molar teeth caries

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age of 8 to 12 years, Class 1 caries penetrates into the dentin of deciduous molars, Frankel Behavioral Index Grade 2 to 3, No previous history of dental treatment

Exclusion criteria:

Coagulation disorder, Severe dental caries, Pulp tooth involvement, Mental or cognitive disorder

Age

From **8 years** old to **12 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Random assignment of the patients to the intervention and control groups through the drawing of lots. To do this, we prepare three sheets and write "intervention 1" on one sheet and "intervention 2" on another, and "control" on the third one. Then, by referring each patient, one of the sheets will be randomly taken and the patient will be assigned to the intervention or control group.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research and Technology,
Hamadan University of Medical Sciences, Shahid
Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Approval date

2020-07-12, 1399/04/22

Ethics committee reference number

IR.UMSHA.REC.1399.375

Health conditions studied

1

Description of health condition studied

Anxiety

ICD-10 code

F06.4

ICD-10 code description

Anxiety disorder due to known physiological condition

Primary outcomes

1

Description

The mean score of anxiety

Timepoint

Before the intervention and immediately after that

Method of measurement

Using the Modified Child Dental Anxiety Scale (MCDAS) and Face Image Scale (FIS) and Face, Legs, Activity, Cry, and Consolability (FLACC) questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Using acupressure bracelet with push button at point P6 five minutes before repairing tooth decay up to one minute after work

Category

Treatment - Devices

2

Description

Intervention group 2: Using conventional bracelet without push button at point P6 five minutes before repairing tooth decay up to one minute after work

Category

Treatment - Devices

3

Description

Control group: Repairing tooth decay without using bracelet

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

School of Dentistry in Hamadan city

Full name of responsible person

Shiva Ansari

Street address

School of Dentistry, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

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ansarishiva730@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Saeid Bashirian

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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

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Shiva Ansari

Position

Dentistry 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

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Full name of responsible person

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Position

Pediatric Dentist

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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Person responsible for updating data

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Jalal Poorolajal

Position

Professor of Epidemiology

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

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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

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