Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison the effect of acupressure and music on the severity of venipuncture pain in children

Protocol summary

Study aim
The aim of this study was to compare the effectiveness of acupressure and music on pain intensity during needle insertion in children.

Design
Randomized Clinical trial without blindness, with control group, with a parallel group design on 90 hospitalized children that requires venous line insertion.

Settings and conduct
This study will be performed in the pediatric and pediatric emergency department of Amir Al-Momenin Hospital in Semnan. In the first group (acupressure), the pressure on the Hego point will perform by a trained nurse for 5 minutes, from 3 minutes before the start to the end of venipuncture with the fingertips or thumb. For the second group (music), a happy childish song without words and in accordance with Iranian culture will be played for the child through headphones for 5 minutes from 3 minutes before the venipuncture until the end of the venipuncture. The control group did not receive any intervention (except for routine hospital interventions).

Participants/Inclusion and exclusion criteria
Inclusion criteria: A child between 3 and 6 years old who needs a venipuncture and is alert; The patient's condition should be such that it is possible to spend time doing massage and playing music. Exclusion criteria: Receiving any sedative, hypnotic and analgesic medication; The nurse failure in the first attempt at venipuncture; Convulsions or any life-threatening conditions during the study; Being under chemotherapy.

Intervention groups
The study groups include children admitted to the pediatric ward and pediatric emergency department who need a venous line insertion. The first intervention group receives acupressure (Hego point massage). The second intervention group receives a childish, happy, non-verbal music in accordance with Iranian culture. The control group receives only routine interventions.

Main outcome variables
Pain intensity during needle insertion

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120109008665N15**
Registration date: **2021-12-06, 1400/09/15**
Registration timing: **prospective**

Last update: **2021-12-06, 1400/09/15**
Update count: **0**

Registration date
2021-12-06, 1400/09/15

Registrant information

Name
Hassan Babamohamadi

Name of organization / entity
Semnan University of Medical Sciences

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-12-16, 1400/09/25

Expected recruitment end date
2022-09-21, 1401/06/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison the effect of acupressure and music on the severity of venipuncture pain in children

Public title
Comparison the effect of acupressure and music on the severity of venipuncture pain in children

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
A child between 3 and 6 years old who needs a venipuncture and is alert The patient's condition should be such that it is possible to spend time doing massage and playing music Parents are not included in the group of medical and health personnel Having relative physical and mental health

Exclusion criteria:
Receiving any sedative, hypnotic and analgesic medication The nurse failure in the first attempt at venipuncture Convulsions or any life-threatening conditions during the study Being under chemotherapy

Age
From **3 years** old to **6 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
Assignment of samples (to two experimental groups and one control group) will be done by simple random method using sealed envelopes. 90 envelopes with one of the letters A, M or C in them (30 envelopes each) will be prepared and the selection of the envelope will be done randomly by the child's parents. In this method, the letter A represents the acupressure group, the letter M represents the music group and the letter C represents the control group. In this way, the number of samples of all three groups will be random and equal.

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
Semnan University of Medical Sciences

Street address
Vice Chancellor of Research and Technology, Semnan University of Medical Sciences, Basidj Blv, Semnan, Iran

City
Semnan

Province
Semnan

Postal code
3519899951

Approval date
2021-11-30, 1400/09/09

Ethics committee reference number
IR.SEMUMS.REC.1400.222

Health conditions studied

1

Description of health condition studied
Pain intensity during venipuncture in children aged 3-6 years

ICD-10 code
G89.18

ICD-10 code description
Other acute postprocedural pain

Primary outcomes

1

Description
Pain intensity

Timepoint
Immediately after the intervention

Method of measurement
Pain intensity will be measured by the Oucher Scale.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In the first group of the test (Hego point acupressure), the pressure on the Hego point is received for 5 minutes, from 3 minutes before the start of the venipuncture to the end of the venipuncture with the fingertips or thumb rotated by a trained nurse. In this way, the Hego point of the child's free hand (the hand in which the cannulation is not performed) is subjected to a moderate rotational pressure counterclockwise. There is

a 30-second break for every 1 minute of pressure.

Category

Prevention

2

Description

Intervention group: For the second group of the test (music), a happy childish non-verbal song in accordance with Iranian culture will be played for the child through headphones for 5 minutes from 3 minutes before the venipuncture to the end of the venipuncture.

Category

Prevention

3

Description

Control group: The control group did not receive any intervention (except for routine hospital interventions).

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Amir Al-Momenin Hospital in Semnan

Full name of responsible person

Hassan Babamohamadi

Street address

Amir-al-Momenin medical-educational & research center, Shaheed Mostafa Khomeini Blvd., Imam Hossein Sq., Semnan. Iran.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Parviz Kokhaei

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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

Semnan 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

Semnan University of Medical Sciences

Full name of responsible person

Hassan Babamohamadi

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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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