

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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 Hegu 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 (Hegu 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)

Phone

+98 23 3365 4190

Email address

babamohamadi@sem-ums.ac.ir

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.

City

Semnan

Province

Semnan

Postal code

3519734731

Phone

+98 23 3346 0055

Fax

+98 23 3346 1580

Email

amir.hospital@semums.ac.ir

Web page address

https://amirhos.semums.ac.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Semnan University of Medical Sciences

Full name of responsible person

Parviz Kokhaei

Street address

Semnan University of Medical Sciences, Vice

Chancellor of Research and Technology, Basidj Blv, Semnan, Iran

City

Semnan

Province

Semnan

Postal code

3519899951

Phone

+98 23 3345 1336

Email

rds@semums.ac.ir

Web page address

http://rtvc.semums.ac.ir

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

Street address

Nursing and Midwifery Faculty, Semnan University of Medical Sciences, 5 Kilometers of Damghan Road, Semnan, Iran

City

Semnan

Province

Semnan

Postal code

3513138111

Phone

+98 23 3365 4192

Fax

+98 23 3365 4209

Email

babamohammady2007@gmail.com

Person responsible for scientific 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

Street address

Nursing and Midwifery Faculty, Semnan University of Medical Sciences, 5 Kilometers of Damghan Road, Semnan, Iran

City

Semnan

Province

Semnan

Postal code

3513138111

Phone

+98 23 3365 4192

Fax

+98 23 3365 4209

Email

babamohammady2007@gmail.com

Person responsible for updating data

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

Street address

Nursing and Midwifery Faculty, Semnan University of Medical Sciences, 5 Kilometers of Damghan Road, Semnan, Iran

City

Semnan

Province

Semnan

Postal code

3513138111

Phone

+98 23 3365 4192

Fax

+98 23 3365 4209

Email

babamohammady2007@gmail.com

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