Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison the effects of active distraction and Shen Men point massage on pain and anxiety during venipuncture in children 4-7 year old hospitalized

Protocol summary

Study aim
Comparison the effects of active visual distraction and Shen Man point massage on pain and anxiety during venipuncture in 4-7 year old children hospitalized in Ekbatan Hospital, 1404

Design
Clinical trial with intervention and control groups, single-blind, randomized

Settings and conduct
The study environment is the pediatric inpatient wards of Ekbatan Hospital in Hamadan. The test and control samples will be selected from among the children who meet the inclusion criteria for the study using a stratified random sampling method. The samples will be divided into three groups using a table of generated random numbers.In the massage group, acupressure point massage was performed five minutes before venipuncture, and then venipuncture was performed. In the distraction group, half-prepared emoticons were completed by the child five minutes before venipuncture. Anxiety scales were completed before, during, and after venipuncture using the Purey instrument, and pain intensity during venipuncture using the Wang Baker instrument by the evaluator.

Participants/Inclusion and exclusion criteria
Entry requirements: Hospitalized child 4 to 7 years old, having healthy organs and skin in the hand, not using painkillers 3 hours before venipuncture, the child is alert to time, place and person, not having mental retardation, the child is hospitalized for the first time, has experienced a second venipuncture during hospitalization, has no pain during venipuncture, has not experienced a painful procedure 24 hours before .Not have traumatized venipuncture and have only had one previous successful venipuncture. Exclusion criteria: unwillingness to continue participating in the study, failure in the first venipuncture, worsening of the child's medical condition

Intervention groups
Intervention groups (Shen Man point massage, active distraction) Control group

Main outcome variables
Pain, anxiety

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190130042555N2**
Registration date: **2026-05-21, 1405/02/31**
Registration timing: **registered_while_recruiting**

Last update: **2026-05-21, 1405/02/31**
Update count: **0**

Registration date
2026-05-21, 1405/02/31

Registrant information

Name
Tayebeh Hasantehrani

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2026-05-20, 1405/02/30

Expected recruitment end date

2026-08-21, 1405/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effects of active distraction and Shen Men point massage on pain and anxiety during venipuncture in children 4-7 year old hospitalized

Public title

Comparison the effects of active distraction and Shen Men point massage on pain and anxiety during venipuncture in children 4-7 year old

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Hospitalized child 4 to 7 years old (48 to 83 months) Having healthy organs and skin in the hand Do not use painkillers for at least 3 hours before venipuncture. The child's first hospitalization Second experience of venipuncture during hospitalization Has not had a traumatic venipuncture and has only had one previous successful venipuncture Have informed consent to undergo the procedure At least 24 hours have passed since the child was hospitalized.

Exclusion criteria:

Failure to obtain a vein the first time Aggravation of the child's condition

Age

From **4 years** old to **7 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **144**

Randomization (investigator's opinion)

Randomized

Randomization description

Sampling and Randomization Initially, all hospitalized children aged 4–7 years who met the inclusion criteria were stratified based on age (4–5 years and 6–7 years) and gender (female/male) in order to balance the distribution of these potential confounding variables across the study groups. Within each stratum, a list of eligible children was prepared, and a unique numerical code was assigned to each child. For randomization, a random allocation list for the three groups (active distraction group, Shen Men point massage group, and control group) was prepared in advance by an individual independent of the sampling process using a random numbers table (or computer-generated random numbers). In this list, the allocation sequence of participants to the three groups was arranged using random blocks of equal size (e.g., blocks of six) to ensure that the number of participants in each group remained approximately equal. When each eligible child entered the study, the researcher responsible for data collection assigned the participant to one of the three groups according to the predetermined allocation sequence and the order of enrollment, without any personal judgment or interference. In this way, the likelihood of allocation bias was minimized and the principle of randomization was maintained in the study.

Blinding (investigator's opinion)

Single blinded

Blinding description

The study will be single-blind, meaning that the statistician will not know the type of intervention in the groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of Hamadan University of Medical Scieneces

Street address

Hamadan University of Medical Sciences, Shahid Fahmideh Blvd., Pazhohesh Square, Hamadan, Iran

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Approval date

2026-01-24, 1404/11/04

Ethics committee reference number

IR.UMSHA.REC.1404.897

Health conditions studied

1

Description of health condition studied

Pain

ICD-10 code

G89.1

ICD-10 code description

Acute pain, not elsewhere classified

Primary outcomes

1

Description
The effect of active distraction on pain intensity
Timepoint
During venipuncture
Method of measurement
Wang Baker Facial Scale

2

Description
The effect of Shen Men point massage on pain intensity
Timepoint
During venipuncture
Method of measurement
Wang Baker Facial Scale

Secondary outcomes

1

Description
The Impact of Shen Men Point Massage on Anxiety Levels
Timepoint
Before, during, and after venipuncture
Method of measurement
Piyeri Anxiety Visual Scale

2

Description
The Impact of Active Distraction on Anxiety Levels
Timepoint
Before, during, and after venipuncture
Method of measurement
Piyeri Anxiety Visual Scale

Intervention groups

1

Description
intervention Group:In the active distraction group, after providing an introduction, explaining the study objectives, and obtaining informed consent from the parents and the child, the child—accompanied by the mother—is taken to the venipuncture room. The room environment is standardized and calming (with soft lighting and free of additional stimuli). First, the Piyeri Anxiety Scale is completed by an assessor.Three semi-prepared cartoon animal templates (such as lion, rabbit, and elephant), designed based on psychological principles of visual attractiveness, along with accessories such as stickers, child-safe scissors, and colored pencils, are provided to the mother and child. They are given 5 minutes to collaboratively complete and personalize the chosen figure. The researcher actively assists the mother and child during this stage.The completed figure is then gently attached to the IV catheter cover to serve as an engaging visual element. The cover, now decorated with the figure, is handed to the child to hold and interact with during venipuncture.Immediately afterward, venipuncture is performed by a trained and experienced nurse who has not previously met the child during hospitalization and has been instructed to maintain consistent behavior with all participants. During catheter insertion, pain intensity is assessed using the Wong-Baker Visual Analog Scale, and anxiety levels are assessed using the Facial Anxiety Scale by an independent assessor who has been previously trained in scoring and evaluation.Immediately after venipuncture, the Piyeri Anxiety Scale is administered again and recorded by the assessor. Finally, the decorated figure is placed on the IV dressing after the procedure is completed.
Category
Prevention

2

Description
Intervention Group: Acupressure GroupAfter introducing the study, explaining its objectives, and obtaining informed consent from the parents and the child to participate in the research, the child, accompanied by the mother, is taken to the venipuncture room. The room environment is standardized and calming (with soft lighting and free from additional stimuli). First, the Piyeri Anxiety Scale is measured by the assessor.In the presence of the mother, Shen Men point massage is performed by the researcher on the hand opposite to the venipuncture site for five minutes. The massage procedure is conducted as follows: the child lies on the bed, the researcher first washes and warms their hands, then stands beside the child’s bed, applies baby oil to their hands, and performs circular massage on the Shen Men point in a clockwise direction with moderate pressure.The maximum continuous massage duration is one minute, followed by a ten-second pause. This cycle continues until the completion of venipuncture. After five minutes from the start of the massage, venipuncture is performed by a trained and experienced nurse who has not previously met the child during hospitalization and has been instructed to maintain consistent behavior during venipuncture with all children.During the insertion of the intravenous catheter, pain intensity is recorded using the Wong–Baker Visual Analog Scale, and anxiety levels are assessed using the Facial Anxiety Scale by an assessor who has been previously trained in the assessment and scoring procedures. Immediately after the completion of venipuncture, the Piyeri Anxiety Scale is measured again by the assessor and recorded.
Category
Prevention

3

Description
Control GroupAfter introducing the study, explaining its objectives, and obtaining informed consent from the parents and the child to participate in the research, the child, accompanied by the mother, is taken to the

venipuncture room. The room environment is standardized and calming (with soft lighting and without additional stimuli). First, the Piyeri Anxiety Scale is administered by the assessor.Children in this group receive only the routine care of the ward. Venipuncture is then performed by the same skilled nurse, who has not previously seen the child during hospitalization and has been trained to maintain consistent behavior during venipuncture with all participants.During insertion of the intravenous catheter, pain intensity is assessed using the Wong–Baker Visual Analog Scale, anxiety is assessed using the Facial Anxiety Scale, and heart rate is recorded by an assessor who has been previously trained in assessment and scoring procedures. Immediately after completion of the venipuncture, the Piyeri Anxiety Scale is administered again by the assessor and recorded.

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Ekbatan Hospital, Hamadan
Full name of responsible person
Taybeh Hassan Tehrani
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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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
Taybeh Hassan Tehrani
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Associate professor
Latest degree
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Person responsible for updating data

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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