Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Nov 2026

Comparison of the effect of Acupressure and Buzzy on First insertion success and pain related insertion of intravenous catheter (Angiocath) in 3-6 year old children referred to the emergency department

Protocol summary

Study aim

Comparison of the effect of Acupressure and Buzzy on first insertion success and pain related insertion of intravenous catheter (Angiocath) in 3-6 year old children referred to the emergency department of Hakim Hospital of Neyshabour in2024

Design

3-group randomized controlled trial with one control and two parallel intervention groups , involving 84 children (28 per group) matched by gender. Each child who presented for angiocatheter placement and met the study inclusion criteria was randomly assigned to one of the groups based on gender within each block. Randomization was performed using the Random Allocation software.

Settings and conduct

Eligible children presenting to the emergency department of Hakim Neyshabour Hospital will be randomly assigned to either an intervention or control group. Acupressure : The Hugo point is compressed before insertion. Buzzy : The Buzzy is attached to the child's hand before insertion. Control : the angiocatheter is inserted routinely

Participants/Inclusion and exclusion criteria

Inclusion criteria: Physician's order for catheter insertion; Age 3 to 6 years; Informed parental consent; First catheter insertion during this hospitalization Fully alert No pain Exclusion: Catheter insertion site other than the back of the hand Use of sedatives or topical or oral analgesics within 48 hours Bruising, inflammation, wound, or fracture at the catheter insertion site History of chemotherapy, dialysis Specific diseases (thyroid, epilepsy, vascular, diabetes, neurological, edema, blood, hearing, vision, movement) Intellectual disability or cerebral palsy Inability to communicate verbally Diagnosed mental or cognitive disorder

Intervention groups

intervention consists of three groups: Acupressure : Pressing the Hugo point Buzzy : Attaching Buzzy on the child's hand Control : Routine insertion

Main outcome variables

Venipuncture pain ; First insertion success

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240413061475N1**
Registration date: **2024-07-14, 1403/04/24**
Registration timing: **prospective**

Last update: **2024-07-14, 1403/04/24**
Update count: **0**

Registration date

2024-07-14, 1403/04/24

Registrant information

Name
Fateme Hesari
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

2024-08-22, 1403/06/01

Expected recruitment end date

2024-12-21, 1403/10/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effect of Acupressure and Buzzy on First insertion success and pain related insertion of intravenous catheter (Angiocath) in 3-6 year old children referred to the emergency department

Public title
Comparison of the effect of Acupressure and Buzzy on First insertion success and pain related insertion of intravenous catheter (Angiocath)
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
There is a need and a doctor's order to insert the IV catheter The child is 3 to 6 years of age Parents have given informed consent. This is the child's first IV catheterization experience at this case of admission The child is fully alert The child does not have acute or chronic pain, and the child's FLACC pain scale score is zero upon admission
Exclusion criteria:
IV catheter to be inserted in a place other than the back of the hand Usage of sedatives or topical or oral pain relievers within 48 hours before insertion There is bruising, inflammation, wound or fracture near the IV catheterization place or the massage point. The child has a history of chemotherapy and dialysis. The child has cognitive disorders. Specific medical conditions: (blood disorders, thyroid disorders, epilepsy, peripheral vascular disease, diabetes, peripheral neuropathy, edema, blood diseases, mental health problems, hearing and vision problems, motor problems in the lower extremities) Hearing and vision impairments Inability to communicate verbally Intellectual disability or cerebral palsy Diagnosed mental health problem
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: **84**
Randomization (investigator's opinion)
Randomized
Randomization description
Convenience sampling will be used for this study. This means that any individual who enters the treatment center and meets the study's inclusion criteria will be eligible to participate. With a sample size of 84, we aim to recruit 28 participants in each group. We also intend to ensure an equal distribution of girls and boys in each experimental group. Therefore, we will employ a blocked randomization method. We will use blocks of 12 participants each, assigning 4 to the Buzzy group, 4 to the Acupressure group, and 4 to the Control group. There will be three blocks of 12 for girls and three blocks of 12 for boys. Additionally, we will use two additional blocks of 6 to enroll an additional 12 girls and boys. In each block of 6, 2 participants will be assigned to the Acupressure group, 2 to the Buzzy group, and 2 to the Control group. Random allocation will be conducted using the "Random Allocation Software". Each child who comes to the clinic for angiocatheter placement and meets the study's inclusion criteria will be placed in one of these blocks based on gender and will be randomly assigned to one of the interventions From the start of the vascular access process and angiocatheter placement, the research assistant measures the time to vascular access using a stopwatch and records it along with the number of attempts to access the vessels in the clinical data collection checklist. Simultaneously, by carefully observing the child, the assistant enters scores for facial expression, leg movement, activity level, crying, and consolability to assess the pain score in the aforementioned checklist. All interventions are performed outside the venipuncture room and the research assistant is blinded to the type of intervention performed.
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 committees of Sabzevar University of Medical Sciences
Street address
Sohadaye hastei boulevard - Sabzevar university of medical Sciences Campus
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sabzevar
Province
Razavi Khorasan
Postal code
9617913112
Approval date
2024-07-06, 1403/04/16
Ethics committee reference number
IR.MEDSAB.REC.1403.041

Health conditions studied

1

Description of health condition studied
pain related insertion of intravenous catheter (Angiocath)
ICD-10 code
ICD-10 code description

2

Description of health condition studied
first insertion success of intravenous catheter (Angiocath)
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
FLACC instrument pain score
Timepoint
During the intervention
Method of measurement
FLACC instrument pain score(faces, legs, activity, cry, consolability)

2

Description
Number of successful angiocath placement attempts
Timepoint
During the intervention
Method of measurement
Counting the number of times of angiocath placement

3

Description
time of successful angiocath placement attempts
Timepoint
During the intervention
Method of measurement
stopwatch

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:The first intervention group : Acupressure
Category
Rehabilitation

2

Description
Intervention group:The second intervention group: buzzy
Category
Rehabilitation

3

Description
Control group: Control group
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Hakim Hospital
Full name of responsible person
Mohammad Shurvarzi
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Imam Reza Square (AS) - the beginning of Shahid Shushtri Blvd
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Sabzevar University of Medical Sciences
Full name of responsible person
Vice President of Research and Technology of Sabzevar University of Medical Sciences
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Web page address
https://www.medsab.ac.ir/index.aspx?siteid=1&siteid=1&fkeyid=&siteid=1&fkeyid=&siteid=1&pageid=2085

Grant name

Grant code / Reference number

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

Title of funding source
Sabzevar 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
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Position
Assistant Professor of Nursing
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document

All data is potentially shareable after de-identifying individuals.

When the data will become available and for how long

The start of the access period after the publication of the article

To whom data/document is available

All people

Under which criteria data/document could be used

The data can be used with the permission of Dr. Ali Asghar Jesemi Marghzar.

From where data/document is obtainable

Send an email to Dr. Ali Asghar Jesemi Marghzar Email address: jesmiaa@gmail.com

What processes are involved for a request to access data/document

By sending an email to Dr. Ali Asghar Jasemi Marghzar after his approval, the data will be provided to the individual.

Comments