Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of the effects of cold spray and acupressure on pain during venipuncture in hospitalized children

Protocol summary

Study aim
Determining the comparative effect of cold spray and acupressure on pain during venipuncture in hospitalized children

Design
Clinical trial with control group, with parallel, randomized groups, 123 children

Settings and conduct
Approval of the research plan in the university ethics committee. At the beginning of the study, complete the demographic characteristics checklist and the Visual Analogue Scale. Intervention group 1: Cold spray: Interventions will be carried out according to the protocol, for 8 weeks and 1 day per week. Intervention group 2: Acupressure: Interventions will include; 8 sessions, each session will last 1 hour and 1 session per week, and will be carried out for a total of 8 weeks according to the protocol. During and after the venipuncture procedure, the visual analog scale will be completed again. The place of the intervention will be the special venipuncture room in each department.

Participants/Inclusion and exclusion criteria
Admission requirements: Being 6-12 years old. Conditions of non-entry: taking painkillers within 3 hours before or during the study.

Intervention groups
Intervention group 1: Cold spray: Spray puff for 5 seconds at a distance of 15 cm to an area of approximately 5 cm2 at the operation site. After fixing the tourniquet and disinfecting the skin for 60 seconds, intravenous injection will be performed. Intervention group 2: Acupressure: It will be performed from point P6 according to the protocol, which will be performed in 1 session and each session will last 10 minutes. Control group: non-intervention: this training group will not be given.

Main outcome variables
Pain during venipuncture

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200107046044N4**
Registration date: **2025-01-26, 1403/11/07**
Registration timing: **prospective**

Last update: **2025-01-26, 1403/11/07**
Update count: **0**

Registration date
2025-01-26, 1403/11/07

Registrant information
Name
Mohammadsajjad Mousavi
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 61 5242 1065
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-03-30, 1404/01/10

Expected recruitment end date
2025-06-28, 1404/04/07

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Comparison of the effects of cold spray and acupressure on pain during venipuncture in hospitalized children

Public title
Comparison of the effects of cold spray and acupressure on pain during venipuncture
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Ability to communicate and respond to visual pain scales Being 6-12 years old Consent to participate in the study and signing the informed consent form No previous training or participation in studies similar to the current research in the past 6 months
Exclusion criteria:
Unwillingness to participate in the study Unsuccessful venipuncture or need for repeat venipuncture Receiving another painful intervention at the same time as the angiocath Taking sleeping pills, anti-anxiety medications, and antidepressants before the intervention Taking painkillers within 3 hours before or during the study
Age
From **6 years** old to **12 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **123**
Randomization (investigator's opinion)
Randomized
Randomization description
Block random assignment will be done in such a way that according to the number of study groups (three groups) consisting of intervention 1 (Cold spray), intervention 2 (Acupressure) and control and calculated based on the factorial law, i.e. 3!= 3×2×1= 6, all the possible arrangement modes of people will be compiled based on the table below, considering A for intervention group 1 (Cold spray), B for intervention group 2 (Acupressure) and C for control group: 1 2 3 4 5 6 CBA CAB BCA BAC ACB ABC Then, since the estimated sample size was 123 people, in each block, three samples, each representative of a study group and their arrangement order was also different, from these blocks, placement sampling will be done. After the study objectives are fully explained, eligible research samples will be selected and, based on the time priority of referral, each of them will be assigned a code. By matching that number with the block random allocation list, the patients participating in the study will be assigned to one of the intervention 1 (Cold spray), intervention 2 (Acupressure), and control groups. This process will continue until the estimated sample size is completed.
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 Yasuj University of Medical Sciences
Street address
Yasuj University of Medical Sciences, Shahid Motahari Blvd., Yasuj, Kohgiluyeh and Boyer-Ahmad, Islamic Republic of Iran
City
Yasuj
Province
Kohgilouyeh-va-Boyrahmad
Postal code
7591741417
Approval date
2025-01-08, 1403/10/19
Ethics committee reference number
IR.YUMS.REC.1403.152

Health conditions studied

1

Description of health condition studied
Pain during venipuncture in hospitalized children
ICD-10 code
G89.18
ICD-10 code description
Other acute postprocedural pain

Primary outcomes

1

Description
Pain score based on Visual Analogue Scale
Timepoint
Severity of pain before, during and after the intervention
Method of measurement
Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Cold spray: In this group, before performing the intravenous intervention, cold spray will be applied for 5 seconds at a distance of 15 cm to an area of approximately 5 cm2 at the surgical site. After securing the tourniquet and then disinfecting the skin for 60 seconds, the researcher will perform the intravenous injection and, in the meantime, the patient's pain will be recorded and measured using a visual analog scale.

Category

Treatment - Devices

2

Description

Intervention group 2: Acupressure: Acupressure will be performed on the P6 point. The P6 point is located on the inner side of the arm and in the cavity between the bones of the forearm, 3 finger widths above the wrist crease. Before applying acupressure, the nurse will first wash the hands and then warm them up to normal body temperature. Then, a massage will be performed from the fingertips to the elbow. For the purpose of the intervention, pressure on the mentioned point will be applied with a force of 3 to 5 kg on both sides in each hand for 3 minutes with the thumb, 3 minutes at each point and 2 minutes of rest, in a circular motion and 2 revolutions per second, so that the patient feels a tingling sensation and mild numbness in his hand. Then, the researcher will insert an angiocatheter (blue, size 22) in the brachial area for all patients while they are sitting on a comfortable chair, and during this time, the patient's pain will be recorded and measured using a visual analog scale. Each patient will have 1 acupressure session, and each acupressure session will last 10 minutes.

Category

Treatment - Devices

3

Description

Control group: non-intervention: There will be no intervention in this group.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Sajjad Hospital

Full name of responsible person

MohammadSajjad Mousavi

Street address

Imam Sajjad Hospital, Next to Hotel Azadi, Yasuj, Kohgiloyeh and Boyerahmad, Islamic Republic of Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yasouj University of Medical Sciences

Full name of responsible person

Seyed Amin Hossaini Motlagh

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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

Yasouj 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

Ahvaz University of Medical Sciences

Full name of responsible person

MohammadSajjad Mousavi

Position

Faculty instructor

Latest degree

Master

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
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