Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Buzzy Device Versus Distraction Cards in Reducing Peripheral Intravenous Cannulation Related-Pain Among School Age Children: A Comparative Randomized Controlled Trial

Protocol summary

Study aim
To compare the efficacy of Buzzy device and Distraction cards in reducing pain during intravenous cannulation in School Age Children.

Design
Comparative, randomized, controlled clinical trial with parallel group design of 192 patients.

Settings and conduct
This study was conducted in the emergency room of Ibn-Al Atheer Hospital, where the study included 192 patients who entered the emergency department and needed intravenous cannulation. They were divided into three groups and the study was conducted on them.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Consent to participate in the study. ages of 6 - 12 years. No difficulty in communication. Not receiving analgesic treatment 6 h before procedure. Exclusion criteria: Skin conditions such as burns, rashes at insertion site. Peripheral vascular disease or compromised peripheral circulation at the intended insertion site (e. g. Peripheral neuropathy, diabetes). History of injections during the last 3 months.

Intervention groups
This stage begins with an intravenous cannulation using one group from 3 groups for each participant: 1- Buzzy device group. 2- Distraction cards group. 3-control group. after cannulation is done successfully, then ask the patient about the severity of the pain by using the Wong-Baker Faces pain scale, and then write the answer on the questionnaire sheet.

Main outcome variables
patient pain during IV cannulation

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240511061742N1**
Registration date: **2024-06-27, 1403/04/07**
Registration timing: **prospective**

Last update: **2024-10-21, 1403/07/30**
Update count: **2**

Registration date
2024-06-27, 1403/04/07

Registrant information

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Name of organization / entity
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-07-01, 1403/04/11

Expected recruitment end date
2024-12-01, 1403/09/11

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Buzzy Device Versus Distraction Cards in Reducing

Peripheral Intravenous Cannulation Related-Pain Among School Age Children: A Comparative Randomized Controlled Trial

Public title
Reducing Pain Associated with Intravenous Cannulation in School Age Children
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Consent to volunteer to participate in the study. Being between the ages of 6 and 12 years. Intravenous cannulation will be applied in right and left hand only. No difficulty in communication, including hearing, visual, speech, and language problems. Not receiving oral or parenteral analgesic treatment before administration. Not receiving chemotherapy treatment.
Exclusion criteria:
Skin conditions such as burns, rashes, open wounds, abscess or boil, severe local infection or cellulitis at the intended insertion site. Peripheral vascular disease or compromised peripheral circulation at the intended insertion site (e. g. Peripheral neuropathy, diabetes, Peripheral artery disease, Raynaud's disease). Blood clotting disorders or increased risk of bleeding (e.g., hemophilia, thrombocytopenia). Anatomical abnormalities or restrictions that impede proper insertion or cause increased risk of complications. History of IV injections during the last 3 months.
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: **192**
Randomization (investigator's opinion)
Randomized
Randomization description
Using the lottery method, which is considered one of the oldest and most ancient methods of selecting a sample randomly, the sample was selected for the study. The names of the three groups were written separately on scraps of paper with a number from 1-64 written on them for each of the three groups and placed inside a container. Then the participating child himself draws a paper from the container containing the name of one of the groups and a serial number from 1-64. The paper is not returned to the container after it is selected.
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
Research Ethical Approval Committee, at the College of Nursing
Street address
Nirgal St.
City
Al-Mosul
Postal code
41001
Approval date
2024-04-25, 1403/02/06
Ethics committee reference number
1431

Health conditions studied

1

Description of health condition studied
Pain management related intravenous cannulation
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Intravenous cannulation related pain (reducing)
Timepoint
The patient's response is measured immediately after the intravenous cannulation to measure the intensity of pain only once.
Method of measurement
Pain scale (Wong-Baker Faces) to measure the intensity of pain as a result of intravenous cannulation intravenous cannulation

Secondary outcomes

empty

Intervention groups

1

Description
After obtaining the patient's consent and explaining the device's operation to him, the device is applied one minute before insertion of the IV cannula over the place where the cannula will be formed, with the cooling wings placed under the device. Then the device is turned on while it is tied to the patient's hand before insertion of

the IV cannula. After one minute, the nurse assisting the researcher forms the cannula. After completing the procedure, the researcher turns off the device and removes it from the child's hand. Then the researcher measures the pain level with the Wong-Baker Faces pain scale.

Category

Treatment - Devices

2

Description

Control group: The intravenous catheter was given using the (standard procedure) followed in the hospital without any intervention or application of any other method by the researcher, only the emergency nurse performed the standard procedure followed, and then the pain intensity was measured using the Wong-Baker pain faces scale by the researcher.

Category

N/A

3

Description

The purpose of the study is explained in a simple way to the child’s parents and to the child as well, and then the distraction card is shown to the child by the researcher before starting to insert the intravenous cannula, and the child is asked about the details on the distraction card (differences or puzzles). While the child is busy concentrating on the distraction card, the intravenous cannula is inserted by the specialist nurse. After completion, the pain level is measured

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Ibn Al-Atheer Hospital
Full name of responsible person
Mohammed Ataallah Ahmed
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
College of Nursing, University of Baghdad
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?
No
Title of funding source
The author of the trial is the funding source
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
Persons

Person responsible for general inquiries

Contact

Name of organization / entity
University of Baghdad, College of Nursing
Full name of responsible person
Mohammed Ataallah Ahmed
Position
student
Latest degree
Ph.D.
Other areas of specialty/work
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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
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Not applicable

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
The researcher is acknowledging the scientific community to have verifiable findings of the study. sharing plan includes making all the related data available through publishing the study report in peer-reviewed reputable journals

When the data will become available and for how long
God willing, once finishing the process of data collection, analysis and successfully publishing the manuscript, all the related files will become available for 6 months after publications

To whom data/document is available
All the related files will be shared with any scientific interested parties.

Under which criteria data/document could be used
It may be used after seeking the author's permission and acknowledging his contribution.

From where data/document is obtainable
The author's professional e-mail that will be available with the published manuscript can be used to contact the author. e-Mail: mohammed.ata2204p@conursing.uobaghdad.edu.iq

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

Comments
The IRCT members deserve sincere gratitude for their sincere efforts to support researchers in achieving their academic goals.

Trial results

Please tick if results have been published
Yes

Summary result posting date
2024-10-21, 1403/07/30

Table of baseline comparison

https://docs.google.com/document/d/1xxY4JpQAtCFleFn5gUL5BT2R3czcmWaP/edit?usp=sharing&ouid=103499106607446295797&rtpof=true&sd=true

Participant flow diagram

https://docs.google.com/document/d/1vxJ4S1XTujV-akGlT5nRxOjdoglF2GtN/edit?usp=sharing&ouid=103499106607446295797&rtpof=true&sd=true

Table of variable outcomes' results

https://docs.google.com/document/d/1G5A1SMSs20Z-UsYRYfmQm8ja7kYpKBqi/edit?usp=sharing&ouid=103499106607446295797&rtpof=true&sd=true

Table of adverse events

non

First publication date

2024-10-21, 1403/07/30

Abstract of published paper