

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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

Name

Mohammed Ataallah

Name of organization / entity

University of Baghdad / college of nursing

Country

Iraq

Phone

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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	
<u>1</u>	
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	
<u>1</u>	
Description of health condition studied	Pain management related intravenous cannulation
ICD-10 code	
ICD-10 code description	
Primary outcomes	
<u>1</u>	
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	
<u>1</u>	
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

Street address

4

City

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41001

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Email

mohammed.ata2204p@conursing.uobaghdad.edu.iq

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

College of Nursing, University of Baghdad

Full name of responsible person

Professor Wissam Jabbar Qassem,phd.Dean

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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

Nursing

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Person responsible for scientific

inquiries

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Position

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Other areas of specialty/work

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Person responsible for updating data

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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>

Email

mohammed.ata2204p@conursing.uobaghdad.edu.iq

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.

Participant flow diagram

<https://docs.google.com/document/d/1vxJ4S1XTujV-akGIT5nRxOjdoglF2GtN/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