# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 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**

**Name**
Mohammed Ataallah

**Name of organization / entity**
University of Baghdad / college of nursing

**Country**
Iraq

**Phone**
+964 770 744 4568

**Email address**
mohammed.ata2204p@conursing.uobaghdad.edu.iq

**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
**Street address**
4
**City**
Mosul
**Postal code**
41001
**Phone**
+964 770 744 4568
**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
**Street address**
4
**City**
Mosul
**Postal code**
41001
**Phone**
+964 770 744 4568
**Email**
mohammed.ata2204p@conursing.uobaghdad.edu.iq
**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
**Street address**
4
**City**
Mosul
**Province**
Nineveh
**Postal code**
41001
**Phone**
+964 770 744 4568
**Email**
mohammed.ata2204p@conursing.uobaghdad.edu.iq

## Person responsible for scientific

## inquiries

**Contact**

**Name of organization / entity**
University of Baghdad, Collège of Nursing

**Full name of responsible person**
Mohammed Ataallah Ahmed

**Position**
student

**Latest degree**
Ph.D.

**Other areas of specialty/work**
Nursing

**Street address**
4

**City**
Mosul

**Province**
Nineveh

**Postal code**
41001

**Phone**
+964 770 744 4568

**Email**
mohammed.ata2204p@conursing.uobaghdad.edu.iq

## Person responsible for updating data

**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

**Street address**
4

**City**
Mosul

**Province**
Nineveh

**Postal code**
41001

**Phone**
+964 770 744 4568

**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.

## 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**