Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Sep 2026

The Effect of ShotBlocker in Reducing Pain Associated with Peripheral Intravenous Cannulation in School Age Children: A Randomized Controlled Trial (RCT)

Protocol summary

Study aim
To compare the efficacy of ShotBlocker and ShotBlocker placebo in reducing pain during intravenous cannulation (IV) in School Age Children(6-12 years).

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 three Wasit hospitals, 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
The 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. The 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 injections during the last 3 months.

Intervention groups
This stage begins with intravenous cannulation injection first using a shotblocker or a shotblocker placebo , then ask the patient about the severity of the pain by using Wong-Baker Faces pain scale, and then write the answer on the questionnaire sheet.

Main outcome variables
Reducing pain during intravenous cannulation

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230714058776N1**
Registration date: **2024-01-21, 1402/11/01**
Registration timing: **retrospective**

Last update: **2024-01-21, 1402/11/01**
Update count: **0**

Registration date
2024-01-21, 1402/11/01

Registrant information

Name
Salsabeel Alaa

Name of organization / entity
The University of Baghdad Nursing Collage

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Iraq

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-07-11, 1402/04/20

Expected recruitment end date
2023-12-02, 1402/09/11

Actual recruitment start date

2023-07-14, 1402/04/23

Actual recruitment end date

2023-12-04, 1402/09/13

Trial completion date

2024-04-18, 1403/01/30

Scientific title

The Effect of ShotBlocker in Reducing Pain Associated with Peripheral Intravenous Cannulation in School Age Children: A Randomized Controlled Trial (RCT)

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 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

- Participant

Sample size

Target sample size: **128**

Actual sample size reached: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

In order to maintain a transparent & scientific-based randomization process, simple randomization will be used in assigning participants to 2 intervention & control groups, assuming that each participant has an equal chance of being assigned to any group. The simple randomization procedure would involve throwing a dice (eg, below & equal to 3 = control, over 3 =treatment). No allocation concealment will be carried out.

Blinding (investigator's opinion)

Single blinded

Blinding description

Blinding description refers to the process of concealing certain information from participants or researchers in a study or experiment. This is typically done to minimize bias and ensure the integrity of the results. In the context of a randomized control trial, blinding refers to keeping participants and/or researchers unaware of certain details, such as the treatment assignment or the group to which participants belong (e.g., experimental group or control group). This helps to ensure that the study's outcomes are not influenced by expectations or preferences, and that the results are more reliable and objective.

Placebo

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

Twenty Street

City

Al-Zubaidiyah

Postal code

10001

Approval date

2023-11-22, 1402/09/01

Ethics committee reference number

2

2

Ethics committee

Name of ethics committee

Research Ethical Approval Committee, at the College of Nursing

Street address

Twenty Street

City

Al-Zubaidiyah

Postal code

10001

Approval date

2023-11-22, 1402/09/01

Ethics committee reference number

2

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 after giving the intravenous cannulation directly to measure the intensity of pain.
Method of measurement
Pain scale (Wong-Baker Faces) to measure the intensity of pain as a result of intravenous cannulation

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In the beginning, the patient’s consent is taken, and then a lottery is made to choose the intervention, either Shotblocker or ShotBlocker placebo, then a fill questionnaire, and then the intervention is performed by one of the methods, then the pain intensity is measured using Wong-Baker Faces pain scale. Control group: the intravenous cannulation is given using the traditional method, and then the pain intensity is measured using Wong-Baker Faces pain scale .
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Al-Azizia hospital, Al-Nomania hospital
Full name of responsible person
Salsabeel Alaa Nasser
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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
Other

Person responsible for general inquiries

Contact
Name of organization / entity
University of Baghdad,College of Nursing
Full name of responsible person
Salsabeel Alaa Nasser
Position
Student
Latest degree
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Other areas of specialty/work
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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
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Not applicable

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

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: salsabeel.alaa2204m@conursing.uobaghdad.edu.iq

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

Comments
Profound appreciations are due to the IRCT members for their genuine efforts in helping researchers fulfilling their academic endeavors.