

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

Country

Iraq

Phone

+964 774 023 1025

Email address

salsabeel.alaa2204m@conursing.uobaghdad.edu.iq

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
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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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Phone

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salsabeel.alaa2204m@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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Twenty Street

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Wasit

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Email

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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

Master

Other areas of specialty/work

Nursing

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Person responsible for scientific inquiries

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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.