Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effect of Shot blocker and Cold Spray on Venipuncture Pain among Blood Donors: A Randomised Controlled Trial

Protocol summary

Study aim
1. To evaluate the effect of shotblocker on pain during venipuncture in adult blood donors. 2. To evaluate the effect of cold spray on pain during venipuncture in adult blood donors. 3. To Compare between shotblocker and cold spray effect on pain during venipuncture in adult blood donors. 4. To find out the association between demographics and level of pain in both shot blocker and cold spray on pain during venipuncture in adult blood donors.

Design
Randomized control trial (one control group and two study groups) design study

Settings and conduct
This study was conducted at the main blood bank in Baquba Teaching Hospital in Diyala Governorate in Iraq.

Participants/Inclusion and exclusion criteria
Subjects eligible for inclusion whom male and female adult blood donors (18 years and above), Volunteering to participate in the study and giving a written consent form, Read and write, and had no sign of (pain, hematoma, necrosis, scar, incision or infection) on the skin around the venipuncture site, and had no analgesic drug for the last six hours. They were excluded if they refused participation, significantly impaired vision, altered mental state, suffered from skin disease associated with cold intolerance (e.g. Raynaud's disease), had vision and hearing problems, sensory-motor deficit, diabetes, peripheral vascular disease, or neuropathy, Wound, burn, scar tissue, etc. on the skin around the venipuncture site.

Intervention groups
Interventional group: Before administration, participants will be given the questionnaire to fill out in order to assess their pain. Then, each participant in intervention groups will be applied a shotblocker and cold spray. Immediately after administering instruments (shotblocker and cold spray), the questionnaire will be given again to mark points in a visual analog scale to assess their venipuncture pain.

Main outcome variables
Venipuncture pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20221223056900N1**
Registration date: **2023-01-01, 1401/10/11**
Registration timing: **prospective**

Last update: **2023-01-01, 1401/10/11**
Update count: **0**

Registration date
2023-01-01, 1401/10/11

Registrant information

Name
Ali Abdalreda

Name of organization / entity
University of baghdad /college of nursing

Country
Iraq

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-01-10, 1401/10/20

Expected recruitment end date
2023-04-10, 1402/01/21

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of Shot blocker and Cold Spray on Venipuncture Pain among Blood Donors: A Randomised Controlled Trial

Public title
Effect of Shot blocker and Cold Spray on Venipuncture Pain among Blood Donors: A Randomised Controlled Trial
Purpose
Health service research
Inclusion/Exclusion criteria
Inclusion criteria:
Subjects eligible for inclusion whom male and female adult blood donors (18 years and above). Volunteering to participate in the study and giving a written consent form Read and write There was no sign of (pain, hematoma, necrosis, scar, incision, or infection) on the skin around the venipuncture site, and no analgesic drug for the last six hours.
Exclusion criteria:
They were excluded if they refused participation significantly impaired vision altered mental state suffered from skin disease associated with cold intolerance (e.g. Raynaud's disease) had vision and hearing problems sensory-motor deficit, diabetes, peripheral vascular disease, neuropathy, Wound, burn, scar tissue, etc. on the skin around the venipuncture site.
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **300**
Randomization (investigator's opinion)
Randomized
Randomization description
In order to maintain a transparent and scientific-base randomization process, systematic sampling methods be used in assigning participants (individuals: blood donors), to intervention (shotblocker or cold spray) and control group, assuming that each participant has an equal chance of being assigned to any group. firstly, defined will the target population, Then. estimate the sampling interval, is calculated by dividing the population size (1500) by the desired sample size (300) with a fixed periodic interval (5) that considers the starting point.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

1

Registry name
Secondary trial Id
Registration date
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee in college of Nursing at university of Baghdad
Street address
No. 7, West Arghavan Ave., Farahzadi Blvd., Qods Town,
City
Baqubaha
Postal code
32001
Approval date
2022-11-27, 1401/09/06
Ethics committee reference number
2

Health conditions studied

1

Description of health condition studied
Blood donation required venipuncture performed by inserting a large bore needle (16G or 18G) into a peripheral vein, usually within the antecubital fossa (Myers & Collins ,2022), also Blood donation is one of the most frequent reasons for venipuncture, which is also one of the most frequent invasive medical procedures in general (Simundic et al.,2015) .Venepuncture-related complications can include the pain, development of haematomas, nerve damage, arterial puncture, petechiae, allergies, phobia, infections, fainting , haemorrhaging, and thromboembolism (Buowari,2013). Tee, (2015) stated that venipuncture often performed by nurses, which cause pain to patients. also, other study reported blood donors who undergo venipuncture frequently feel stress and extreme pain (Ialongo & Bernardini, 2016). Pain is an uncomfortable emotion and a physical sensation that might indicate either real or potential tissue injury and Pain not only results from disease itself but may also be derived from invasive diagnosis and treatment interventions (Aydede ,2019). Pain caused by venipuncture become problematic (Shafii et al.,2019), causing high levels of anxiety (McMurtry et al.,2015) and emotional consequences including needle-related phobia (Sokolowski et al.,2010). Therefore, it is essential to control pain throughout medical procedure (Marcy et al., 2017), and it is the primary responsibility of nurses to use the most effective methods to manage pain (Blinderman,2016).

ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
The primary outcome variable is the pain related to Venipuncture in blood donors that can be changed based on shotblocker or cold spray.
Timepoint
Immediately after applying a shotblocker or cold pray, pain related to venipuncture measuring by a visual analogue scale.
Method of measurement
The visual analogue scale (VAS) will be used to assess the level of pain related to venipuncture.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Use shotblocker on skin blood donors during venipuncture and immediately after venipuncture assesses the severity of pain by visual analogue scale . Intervention group 2 : Use cold spray on skin blood donors during venipuncture and immediately after venipuncture to assess pain severity by visual analogue scale.
Category
Other

2

Description
Control group: For the control group, no intervention will be done (usual care), and assess pain immediately after venipuncture.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Main blood bank in in Diyala governorate in Iraq.
Full name of responsible person
Dialya Health Director.
Street address
No. 7, West Arghavan Ave., Farahzadi Blvd., Qods Town
City
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Ali.Hussein2102m@conursing.uobaghdad.edu.iq

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
University of Baghdad
Full name of responsible person
Ali Abdalreda Hussein
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
University of Baghdad
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
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
University of Baghdad
Full name of responsible person
Ali Abdalreda Hussien
Position
Nurse
Latest degree
Bachelor
Other areas of specialty/work
Nursery
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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
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

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 data will be the results of the questionnaire that contains from two-part, the first part is demographic characteristics and the second part is a visual analogue scale to measure blood donors' pain related to venipuncture in both control and intervention groups.

When the data will become available and for how long
Once the article is published, the data will be available after 6 months of publication. if the article will be published in a subscribed journal, the data will be available after one year because of the policy of subscribed journals.

To whom data/document is available
With academic nurses and any researcher who is interested in the data.

Under which criteria data/document could be used
The data could be used after getting permission via email. also, users need to acknowledge the owner.

From where data/document is obtainable
Users can ask for the data and permission via email. His email is Ali.Hussein2102m@conursing.uobaghdad.edu.iq.

What processes are involved for a request to access data/document
Users can ask for the data and permission via email. His email is Ali.Hussein2102m@conursing.uobaghdad.edu.iq.

Comments