

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 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

Phone

+964 770 075 2984

Email address

ali.hussein2102m@conursing.uobaghdad.edu.iq

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.

AgeFrom **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 spray, 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

Baqubah

Postal code

32001

Phone

+964 770 075 2984

Email

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

Street address

No. 7, West Arghavan Ave., Farahzadi Blvd., Qods Town,

City

Baqubah

Postal code

32001

Phone

+964 770 075 2984

Email

Ali.Hussein2102m@conursing.uobaghdad.edu.iq

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

Street address

No. 7, West Arghavan Ave., Farahzadi Blvd., Qods Town,

City

Baqubah
Province
Dialya
Postal code
32001
Phone
+964 770 075 2984
Email
Ali.Hussein2102m@conursing.uobaghdad.edu.iq

Person responsible for scientific inquiries

Contact

Name of organization / entity
University of Baghdad
Full name of responsible person
Ali Abdalreda Hussein
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Hematology
Street address
No. 7, West Arghavan Ave., Farahzadi Blvd., Qods Town,
City
Baqubah
Province
Dialya
Postal code
32001
Phone
+964 770 075 2984
Email
Ali.Hussein2102m@conursing.uobaghdad.edu.iq

Person responsible for updating data

Contact

Name of organization / entity
University of Baghdad
Full name of responsible person
Ali Abdalreda Hussien
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Hematology
Street address
No. 7, West Arghavan Ave., Farahzadi Blvd., Qods Town,
City

Baqubah
Province
Dialya
Postal code
32001
Phone
+9640770075294
Email
Ali.Hussein2102m@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

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