Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Jul 2026

Comparing the Effect of Using Lidocaine Spray and ShotBlocker on Pain Level During Intramuscular Injection: A Randomized Control Trial

Protocol summary

Study aim
Comparing the effect of using lidocaine spray and shotblockers on pain level during intramuscular injection in adults

Design
An experimental, a randomized controlled trial (RCT) prospective, comparative. design with a minimum sample size of 51 for each group will be used. The total sample size would be 153 subjects

Settings and conduct
The study was conducted in Imam Al-Sadiq General Hospital in the Hilla city. , Iraq

Participants/Inclusion and exclusion criteria
All adult patients (over 18 years) receiving intramuscular injections (Diclofenac Sodium) who are admitted to the emergency department will be included in the study. Patients who refused to participate in the study; individuals with communication difficulties or unconsciousness, those with fibrosis, wounds, or infections at the injection site, individuals involved in Road Traffic Accidents (RTA), stab wounds, or bleeding injuries ,Patients with any disease or condition that interferes with study results will be excluded

Intervention groups
The study used assigning participants (Patients receiving intramuscular injections {diclofenac sodium} who are admitted to the emergency department) to intervention group (shotblocker and lidocaine spray) and control groups. The process will involve a simple randomization procedure wherein participants will select a color from a sealed envelope containing three colors: blue, yellow, and green. Each color corresponds to a group (blue for the ShotBlocker group, yellow for the lidocaine spray group, and green for the control group), and participants will be allocated randomly among these three groups. after injection procedure The researcher introduced the patients to the Visual Analog Scale (VAS) pain intensity scale , patient placing a check in front of the number denoting the degree of the pain.

Main outcome variables
reducing pain during intramuscular injection

General information

Reason for update
Acronym
RCT
IRCT registration information
IRCT registration number: **IRCT20240127060820N1**
Registration date: **2024-02-21, 1402/12/02**
Registration timing: **retrospective**

Last update: **2024-02-21, 1402/12/02**
Update count: **0**
Registration date
2024-02-21, 1402/12/02

Registrant information
Name
Hameed Muslim
Name of organization / entity
Karbala University
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2023-12-01, 1402/09/10
Expected recruitment end date
2024-02-01, 1402/11/12
Actual recruitment start date
2023-12-10, 1402/09/19

Actual recruitment end date
2024-01-28, 1402/11/08
Trial completion date
empty

Scientific title
Comparing the Effect of Using Lidocaine Spray and ShotBlocker on Pain Level During Intramuscular Injection: A Randomized Control Trial

Public title
Comparing the Effect of Using Lidocaine Spray and ShotBlocker on Pain Level During Intramuscular Injection: A Clinical Trial
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Adult participants between the ages of 18 – 60 years old; did not receive analgesics/sedatives during the past 24 hours; voluntary participated in the study; patient did not have fibrosis, wound, infection and tenderness in the injection site: patients who entered the Emergency Department and were prescribed analgesics by the physicians: have no problems communicating and are fully conscious: patient not have diseases Gastric Ulcers and Asthma.
Exclusion criteria:
Patients who refused to participate in the study; individuals with communication difficulties or unconsciousness, those with fibrosis, wounds, or infections at the injection site, individuals involved in Road Traffic Accidents (RTA), stab wounds, or bleeding injuries. Patients receiving medication (such as antibiotics or analgesics) intravenously or intramuscularly, pregnant women, and individuals experiencing side effects of Diclofenac Sodium like gastric ulcers and asthma were also excluded from the study
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **150**
Actual sample size reached: **156**
Randomization (investigator's opinion)
Randomized
Randomization description
In order to maintain a transparent and scientifically based randomization process, stratified randomization will be used in assigning participants (Patients receiving intramuscular injections {diclofenac sodium} who are admitted to the emergency department) to intervention (shotblocker and lidocaine spray) and control groups. This method ensures that each participant has an equal chance of being assigned to any group. The process will involve a simple randomization procedure wherein participants will select a color from a sealed envelope containing three colors: blue, yellow, and green. Each color corresponds to a group (blue for the ShotBlocker group, yellow for the lidocaine spray group, and green for the control group), and participants will be allocated randomly among these three groups
Blinding (investigator's opinion)
Single blinded
Blinding description
the single-blind technique, was employed as the researcher needs to know how the subjects will be treated. Therefore, the study was done whereas the participants were unaware of the interventional group. With the use of this blinding technique, the study results are well shielded from the subject knowledge of the treatment assignment . There have been (153) patients in the sample. Both the intervention groups and the control group obtained an equal number of these subjects .
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee in College of Nursing at University of Karbala
Street address
Al Iskan Street, Al Hussein District
City
Karbala,
Postal code
10053
Approval date
2023-11-19, 1402/08/28
Ethics committee reference number
23519

Health conditions studied

1

Description of health condition studied
Patients receiving intramuscular injections {diclofenac sodium} who are admitted to the emergency department
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
The primary outcome variable is the level of pain during intramuscular injection that can be changed based on using shotblocker and lidocaine spray
Timepoint
immediate after intervention (intramuscular injection) using visual analog scale and after three weeks to measurement of the primary outcome
Method of measurement
measurement pain level after intramuscular injection by using visual analog scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The study included adult patients who were chosen based on the aforementioned criteria. The study was carried out in the emergency departments with patients who had been prescribed diclofenac sodium by their physicians. To reassure the participants, the researcher explained the study's aims, duration, and technique in terms of information confidentiality. Following that, the oral and written consents of the patients who will participate in the sample were obtained, as they were randomly divided into three groups (Total 153). This method ensures that each participant has an equal chance of being assigned to any group. The process will involve a simple randomization procedure wherein participants will select a color from a sealed envelope containing three colors: blue, yellow, and green. Each color corresponds to a group (blue for the ShotBlocker group, yellow for the lidocaine spray group, and green for the control group), and participants will be allocated randomly among these three groups .The injection procedure and the randomization method for selecting one of the groups are discussed with participations. The researcher introduced the patients to the Visual Analog Scale (VAS) pain intensity scale before administering the injection, placing a check in front of the number denoting the degree of the pain.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Al-Sadiq General Hospital in the Hilla city.
Full name of responsible person
Hameed Muslim Hashem
Street address
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
University of Kerbala
Full name of responsible person
Hameed Muslim Hashem
Street address
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Email
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Web page address
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Grant name
Grant code / Reference number
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
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
University of Kerbala
Full name of responsible person
Hameed Muslim Hashem
Position
lecture
Latest degree
Master

Other areas of specialty/work
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Person responsible for updating data

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Web page address
https://nursing.uokerbala.edu.iq/wp/en/

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 Patients receiving intramuscular injections {diclofenac sodium} who are admitted to the emergency department for both intervention and control groups,
When the data will become available and for how long
God Willing, 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 the 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. Hameed Muslim is the corresponding author. He will contact whoever he requests the information from. His email is hameed.muslim@s.uokerbala.edu.iq Hameed Muslim works at the Imam Al-Sadiq General Hospital . The address is Al-Hussein neighborhood district, Karbala, Iraq. What processes are involved for a request to access data/document
What processes are involved for a request to access data/document
Users can ask for the data and permission via email. Hameed Muslim is the corresponding author. He will

contact whoever he requests the information from. His email is hameed.muslim@s.uokerbala.edu.iq

Comments