Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Manual Pressure versus Shotblocker in Reducing Intramuscular Injection-Related Pain: A Comparative Randomized Controlled Trial

Protocol summary

Study aim
To compare the efficacy of ShotBlocker and Manual Pressure in reducing intramuscular (IM) injection-related pain in adults.

Design
Comparative,randomized, controlled clinical trial with parallel group design of 128 patients.

Settings and conduct
This study was conducted in the emergency room of three Wasit hospitals, where the study included 128 patients who entered the emergency department and needed intramuscular injection using the Voltaren ampule. They were divided into three groups and the study was conducted on them.

Participants/Inclusion and exclusion criteria
The inclusion criteria: 18 to 80 years of age, no difficulty in communication, including hearing, visual, speech, and language problems, having two healthy muscles of the same size, and no sensory problems in the ventrogluteal muscles. The exclusion criteria of the study were the presence of scars, redness, bruising, tenderness, and stiffness at the injection site, history of injections in the past two weeks, neuropathy, drug abuse.

Intervention groups
This stage begins with intramuscular injection first using a shotblocker or a manual pressure , then ask the patient about the severity of the pain by using visual analogue scale (VAS) score, and then write the answer on the questionnaire sheet.

Main outcome variables
Reducing intramuscular-related pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220929056057N1**
Registration date: **2023-01-01, 1401/10/11**
Registration timing: **registered_while_recruiting**

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

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

Registrant information

Name
Safaa Ezzat

Name of organization / entity

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-12-04, 1401/09/13

Expected recruitment end date
2023-03-14, 1401/12/23

Actual recruitment start date
2022-12-15, 1401/09/24

Actual recruitment end date
2023-03-15, 1401/12/24

Trial completion date
2023-09-19, 1402/06/28

Scientific title
Manual Pressure versus Shotblocker in Reducing Intramuscular Injection-Related Pain: A Comparative Randomized Controlled Trial

Public title
Reducing Intramuscular Injection-Related Pain

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

18 to 80 years of age. Patients did not use analgesics or sedatives with central or peripheral effects. No difficulty in communication, including hearing, visual, speech, and language problems. Having two healthy muscles of the same size. No sensory problems in the ventrogluteal muscles.

Exclusion criteria:

The presence of scars, redness, bruising, tenderness, and stiffness at the injection site. Patients use analgesics or sedatives with central or peripheral effects. History of injections in the past two weeks. Presence of neuropathy. Drug abuse.

Age

From **18 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

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)

Not blinded

Blinding description

Placebo

Not 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

Military district

City

Al-zubydia

Postal code

10001

Approval date

2022-12-04, 1401/09/13

Ethics committee reference number

3

Health conditions studied

1

Description of health condition studied

Pain management related intramuscular injection.

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Intramuscular related pain (reducing)

Timepoint

The patient's response after giving the intramuscular injection directly to measure the intensity of pain

Method of measurement

Pain scale(VAS)score to measure the intensity of pain as a result of intramuscular injection

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group: In the beginning, the patient’s consent is taken, and then a lottery is made to choose the intervention, either Shotblocker or Manuel Presser, then a questionnaire is given to him, and then the intervention is performed by one of the methods, then the pain intensity is measured using visual analogue scale (VAS)score. Control group: the intramuscular injection is given using the traditional method in the posterior gluteal region, and then the pain intensity is measured using visual analogue scale (VAS)score.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Azizia hospital, Al-Nomania hospital

Full name of responsible person

Safaa Ezzat hassan

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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 Hudda paqer, phd. Dean
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safaaehassan96@gmail.com
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
Safaa Ezzat Hassan
Position
Student
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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: safaa.ezzat2102m@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.