Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison Of The Effects Of Skin Pulling, Pressure And Quick Release Of Muscle By Z Methods On Pain Induced By Intramuscular Injection.

Protocol summary

Study aim
Comparison of the effects of skin pulling, pressure and quick release of muscle by Z method on pain Induced by Intramuscular Injection.

Design
This study is done on 63 patients taking metocarbamol and have entry requirements. For the patient, two injections of 5 Cc will be done in Z methods and innovative manner.

Settings and conduct
This study is a triple blind clinical trial that will be carried out at Vasei hospital, unit of injection, at Vasei hospital. each patient will experience two injection methods. In this study, the patient, the pain assessor and the statistical analyst of how to do the injection are unaware.

Participants/Inclusion and exclusion criteria
Ages 16 to 60, lack of communication problems such as auditory, visual, speech and common language, The same volume In the patient's venterogluteal muscles and having written consent, two healthy muscles, and no sensory problem have two equal volume muscles and non-inclusion criteria include scarring, redness, bruising, sensitivity and stiffness at the injection site, history of injection in the past two weeks, neuropathy, severe pain due to illness and severe fear of injection, individuals with BMI below 15 and over 35, drug use was a history of diabetes.

Intervention groups
Intervention group:Injection by inventive method (pulling skin, pressure and rapid release of muscle) after dragging and applying deep pressure with the needle entry, the muscle quickly released. Control group: Injection by Z method and without quick release of muscle.

Main outcome variables
In this study, the pain after each injection is evaluated using VAS.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20131113015393N5**
Registration date: **2019-04-12, 1398/01/23**
Registration timing: **retrospective**

Last update: **2019-04-12, 1398/01/23**
Update count: **0**

Registration date
2019-04-12, 1398/01/23

Registrant information

Name
Narjes Heshmati Far

Name of organization / entity
Sabzevar University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-01-14, 1397/10/24

Expected recruitment end date
2019-02-28, 1397/12/09

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison Of The Effects Of Skin Pulling, Pressure And Quick Release Of Muscle By Z Methods On Pain Induced By Intramuscular Injection.

Public title
The Effects Of Skin Pulling, Pressure And Quick Release Of Muscle By Z Methods On Pain.

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Ages 16 To 60 The Lack Of Communication Problems Such As Hearing, Visual, Speech And Common Language The Same Volume In The Patient's Venterogluteal Muscle Having Written Consent

Exclusion criteria:
Having Scar, Redness, Bruising, Sensitivity And Stiffness At The Injection Site, Neuropathy Having A History Of Injections In The Last Two Weeks Severe Pain Caused By The Disease Severe Fear Of Injection

Age
From **16 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **63**
More than 1 sample in each individual
Number of samples in each individual: **2**
Injection in the ventrogluteal muscle of the left and right

Randomization (investigator's opinion)
Randomized

Randomization description
By Tap And Line For Example, In The Venterogluteal Muscle Of The Right Is A z Injection And Inventive In The Venterogluteal Muscle Of The Left. And In The Next, The Sequence Is Change.

Blinding (investigator's opinion)
Triple blinded

Blinding description
In This Study, All Injections Were Performed By A Qualified Nurse. Participants Were Unaware Of The Injection Method And After Injection, The Pain Assessment Was Done By Another Nurse Who Was Also Unaware Of The Injection Method. Finally, The Statistical Analyst Did Not Know How To Inject, So That Injections A And B Were Delivered To The Statistician.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Sabzevar University of Medical Sciences

Street address
School of Nursing and Midwifery; Shohadaye Hasteii Boulevard, Sabzevar

City
Sabzevar

Province
Razavi Khorasan

Postal code
9617913112

Approval date
2019-01-11, 1397/10/21

Ethics committee reference number
IR.MEDSAB.REC.1397.098

Health conditions studied

1

Description of health condition studied
Pain caused by muscle injection

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Pain

Timepoint
In this study, the pain after each injection is evaluated using Visual Analogue Scale, so that each patient is dosed twice and immediately after each injection, and the distance between the two injections in each patient is just as much as the pain questionnaire.

Method of measurement
Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Injection by inventive method (pulling skin, pressure and rapid release of muscle) after dragging and applying deep pressure with the needle

entry at 90 °, the muscle quickly released and injection after aspiration at 1 Cc In 10 seconds to be in this method, The actual release of the muscle causes the needle to enter, and the needle movement is inactive by the dominant hand and the main role is to remove the pressure from the muscle by the non-dominant hand. All injections were performed using a 5-cc syringe with a needle number 22Mm, and the air locking technique was performed with two 0.2cc in all injections. The use of alcohol-impregnated cotton was used to sterilize injection site. Meanwhile, a gap was not considered between the two injections except the completion of the pain assessment questionnaire.

Category

Prevention

2

Description

"Control group:"In Z injection methods, the pressure was applied and after pulling the skin between the fingers and the needle pointed in a dart manner with A 90 degree angle entered and after aspiration, injected at 1Cc in 10 seconds. The difference is that in addition pulling skin and pressure, rapid release of the skin can help reduce pain in the inventive method.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Sabzevar Vasei hospital

Full name of responsible person

Mehdi Ilkhani

Street address

Shohadaye Hasteii Boulevard, Sabzevar Vasei hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Mostafa Rad

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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

Sabzevar University of Medical Sciences

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

Sabzevar University of Medical Sciences

Full name of responsible person

Narjes Heshmatifar

Position

Faculty member of Sabzevar University

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Position
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be 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