

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

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

Protocol summary

Study aim

The Purpose Of This Study Was To Determine The Effect Of Using Stretching On The Skin, Pressure And Rapid Release Of Muscle To Reduce Injection Pain Compared With Standard Injection Methods.

Design

This Study Is Done On 28 Patients Taking Metocarbamol And Have Entry Requirements. For The Patient, Two Injections Of 5 Cc Will Be Done In Conventional And Innovative Manner. Random Assignments Will Be Made By Tap And Line For Example, In The Dorsogluteal Muscle Of The Right Is A Common Injection And Inventive In The Dorsogluteal Muscle Of The Left. And In The Next, The Sequence Is Change.

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

Entry Criteria For Sampling Including Ages 16 To 60, Lack Of Communication Problems Such As Auditory, Visual, Speech And Common Language, The Same Volume In The Patient's Dorsogluteal 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

This Study Has Two Groups Which For Each Patient, There Are Two Common And Innovative Methods

Main outcome variables

Pulling The Skin, Pressure And Quick Release Of The Muscle

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171231038155N1**

Registration date: **2018-01-29, 1396/11/09**

Registration timing: **retrospective**

Last update: **2018-01-29, 1396/11/09**

Update count: **0**

Registration date

2018-01-29, 1396/11/09

Registrant information

Name

Maryam Salary

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 4464 8905

Email address

salarym94@medsab.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-01-10, 1396/10/20

Expected recruitment end date

2018-01-20, 1396/10/30

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 Conventional Method On Pain Induced By Intramuscular Injection.

Public title

Influence Of Pressure And Rapid Release Of Muscle On The Pain Caused By Muscle Intramuscular Injection

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

The Criteria For Entering The Research Include Ages 16 To 60 The Lack Of Communication Problems Such As Hearing, Visual, Speech And Common Language The Same Volume In The Patient's Dorsogluteal 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: **28**

More than 1 sample in each individual

Number of samples in each individual: **2**

For Each Patient On Dorsogluteal Muscles, Two Conventional And Inventine Injections Are Performed.

Randomization (investigator's opinion)

N/A

Randomization description**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

Considering That This Study Examines The Effect Of Skin Pulling, The Pressure And Quick Release Of Muscle On The Pain Caused By Muscle Injections, This Method Is The First One To Be Done, And It May Be Hard To Understand How This Method Is For The Readers. A Brief Video Of How To Inject Should Be Attached To The Article.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Sabzevar University of Medical Sciences

Street address

Abu Mosalm Street -Abu Moslem 8th , No. 14

City

Sabzevar

Province

Razavi Khorasan

Postal code

9619614479

Approval date

2017-12-11, 1396/09/20

Ethics committee reference number

IR.MEDSAB.REC.1395.141

Health conditions studied**1****Description of health condition studied**

Pain Caused By Muscle Transfusion

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Pain

Timepoint

In This Study, The Pain After Each Injection Is Evaluated Using VAS, 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

VAS

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. Control Group: In The Conventional Injection Method, The Pressure Was Not 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

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

بیمارستان واسعی

Full name of responsible person

مریم سالاری

Street address

سبزوار بیمارستان واسعی راه شهرک توحید

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

دکتر فرشته قراط

Street address

سبزوار - بلوار شهدای هسته ای- بالاتر از مزار شهدای گمنام -

پردیس دانشگاه علوم پزشکی سبزوار - معاونت تحقیقات و فناوری

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Web page address

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Grant name

-222

Grant code / Reference number

12

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

maryam salary

Position

Student of Internal and Surgical Masters

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Sabzevar University of Medical Sciences

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Position

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Person responsible for updating data

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Sabzevar University of Medical Sciences

Full name of responsible person

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Position

Student of Internal and Surgical Masters

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Web page address

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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