Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

A comparative study on the effect of intramuscular injection site selection according to anthropometric and demographic body shape assessment methods on pain injection

Protocol summary

Study aim

Determining thethe effect of intramuscular injection site selection according to anthropometric and demographic body shape assessment methods on pain injection Comparison of the severity of injection pain in two methods of selecting an injection site based on anthropometric and demographic indicators with body shape, body mass index and sex

Design

A clinical trial with a control group, with parallel groups, without blinding, randomized

Settings and conduct

Implementation of the study in the injections section of Vasei Hospital in Sabzevar. The exact location of ventrogluteal and dorsogluteal (DG) sites was determined using V and square method respectively.

Participants/Inclusion and exclusion criteria

Problems in communicating, cognitive problems, having sensory or motor problems, stiffness and sensitivity or history of injection in the site and history of mental illness, diabetes and Norpathy prevents people from entering the study

Intervention groups

1) in the control group all patients received dorsogluteal injection (traditional way). 2) in the anthropometric group, the algorithm presented by Larkin et al. was used to select the site of gluteal injection based on sex, weight, BMI, waist circumference (WC) and anterior superior iliac spine to iliac tubercle (ASIS-IT) 3) in the body shape pattern group, the algorithm presented by Larkin et al. was used to select the site of gluteal injection based on observed body shape indices (OBS), BMI and gender.

Main outcome variables

severity of intramuscular injection pain

General information

Reason for update

After an epidemiologist was added to the research team, the study design changed briefly. Therefore, the corrections made to the study were updated

Acronym

IRCT registration information

IRCT registration number: **IRCT20180826040875N1**
Registration date: **2018-09-29, 1397/07/07**
Registration timing: **prospective**

Last update: **2020-04-10, 1399/01/22**
Update count: **1**

Registration date

2018-09-29, 1397/07/07

Registrant information

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-22, 1397/07/30

Expected recruitment end date

2018-12-21, 1397/09/30

Actual recruitment start date

2018-10-27, 1397/08/05

Actual recruitment end date

2018-12-31, 1397/10/10

Trial completion date

2018-12-31, 1397/10/10

Scientific title

A comparative study on the effect of intramuscular injection site selection according to anthropometric and demographic body shape assessment methods on pain injection

Public title

Does selecting the site of injection based on anthropometric indices and body shape reduces the pain of injection?

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Participants in the research have written consent There is no problem communicating (example: hearing, vision, speech, common language) At least 18 years old and maximum 65 years

Exclusion criteria:

Having very severe pain due to the disease Having a physical (motor or sensory) problem Toughness and tenderness and pain at the injection site Having a former injection site in the last two weeks Patients with psychopathy, diabetes,neuropathy, delirium, dementia, coagulopathy, and those had an extreme fear of injections Use of opiate or non-opiate analgesics 6 hours before enrollment

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **162**

Actual sample size reached: **162**

Randomization (investigator's opinion)

Randomized

Randomization description

Enrolled subjects were randomly assigned to a 1:1 ratio using a web-based random allocation system in undisclosed block sizes of six. There were 168 sequentially numbered opaque sealed envelopes (SNOSE) that contained a group assignment for the subjects. The envelopes were shuffled and distributed to each subject. The registered nurse chose the method of injection after opening the undisclosed envelope.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Three group randomized controlled clinical trial study

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Sabzevar University of Medical Sciences

Street address

Vasei Hospital, Nuclear Martyrs Blvd

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Razavi Khorasan

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9617747431

Approval date

2018-09-24, 1397/07/02

Ethics committee reference number

IR.MEDSAB.REC.1397.037

Health conditions studied

1

Description of health condition studied

pain of intramuscular injection

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

severity of pain after intramuscular injection in gluteal muscles

Timepoint

After injection

Method of measurement

The Visual Analogue Scale (VAS)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Selection of injection site using an algorithm extracted from demographic and anthropometric indices

Category

Treatment - Other

2

Description
Intervention group: Selection injection site with body shape pattern and demographic indicators
Category
Treatment - Other

3

Description
Control group: Injection in the dorsogluteal position
Category
Treatment - Other

Recruitment centers

1

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Sponsors / Funding sources

1

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
The authors received no financial support for the research, authorship, and/or publication of this article.
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Persons

Person responsible for general inquiries

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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