

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Comparison of the Effects of Lidocaine Sprays and Ecupressure on Muscle Pain Injection

Protocol summary

Study aim

Comparison of the Effects of Lidocaine Sprays and Ecupressure on Muscle Pain Injection

Design

A clinical trial with a control group with parallel group design of 252 patients, one blind, randomized control group

Settings and conduct

This study is randomized clinical trial. The research population is the patients who visit the emergency department of Neyshabour 22 Bahman Hospital for intramuscular injection. A demographic questionnaire and a VAS visual analogue instrument will be used to collect the data. The instrument complement will not be aware of the type of injection. Before injection, the method of determining the amount of pain will be taught to the patients and oral consent will be obtained from the patients. Patients in Groups A, B, and C are divided into the following simple random sampling, with the following characteristics: Group A: Intramuscular injection without any intervention Group B: Use of lidocaine sprays before muscle injection Group C: Performing intramuscular injection and performing medicine Pressure in the area (UB 31).

Participants/Inclusion and exclusion criteria

At least 15 years old: The desire to participate in the study

Intervention groups

Group A: Muscle infusion without any intervention Group B: Use of lidocaine spray before intramuscular injection Group C: Perform acupressure before muscle injection

Main outcome variables

Reducing pain in patients

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180110038300N1**

Registration date: **2019-05-25, 1398/03/04**

Registration timing: **prospective**

Last update: **2019-05-25, 1398/03/04**

Update count: **0**

Registration date

2019-05-25, 1398/03/04

Registrant information

Name

Arezoo Davarinia Motlagh Quchan

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-07-01, 1398/04/10

Expected recruitment end date

2020-03-01, 1398/12/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effects of Lidocaine Sprays and Ecupressure on Muscle Pain Injection

Public title

Comparison of the Effects of Lidocaine Sprays and

Ecupressure on Muscle Pain Injection

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
 Age more than 15 years The desire to participate in the study
Exclusion criteria:

Age
From 15 years old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: 252

Randomization (investigator's opinion)
Randomized

Randomization description
Patients are divided into 3 groups A, B and C by permutation blocks. Group A intramuscular injection without any intervention Group B: Use of lidocaine spray before muscle injection Group C: Acupressure before intramuscular injection

Blinding (investigator's opinion)
Single blinded

Blinding description
In this study, the participants were blinded and do not know which of the 3 study groups would be.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Sabzevar University of Medical Sciences

Street address
Sabzevar University of Medical Sciences

City
Sabzevar

Province
South Khorasan

Postal code
9617913114- 96179131

Approval date
2019-03-02, 1397/12/11

Ethics committee reference number

IR.MEDSAB.REC.1397.115

Health conditions studied

1

Description of health condition studied
ICD-10 code
ICD-10 code description

2

Description of health condition studied
 Lidocaine spray
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
 Reduse pain of intramuscular injection
Timepoint
 Immediately after intramuscular injection
Method of measurement
 Visual Analuge Score

Secondary outcomes

1

Description
 Determine of Satisfaction
Timepoint
 After muscle injections
Method of measurement
 check list

Intervention groups

1

Description
 Acupressure
Category
 Treatment - Other

2

Description
 Lidocaine Spray
Category
 Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center

22 Bahman Neyshabour Hospital
Full name of responsible person
Arezo Davarinia Motlagh Quchan
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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?

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

Arezo Davarinia Motlagh Quchan
Position
Faculty member
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Not applicable

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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

All information obtained will be unidentified.

When the data will become available and for how long

After printing the results

To whom data/document is available

Researchers working in medical science universities

Under which criteria data/document could be used

There is no other condition.

From where data/document is obtainable

Student research Comittee

What processes are involved for a request to access data/document

There is no process

Comments